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UNIVERSITY OF ALBERTA

CHARACTERISTICS OF A POTENTIAL DONOR POOL AND EFFECTIVENESS OF ORGAN UTILIZATION

by

PRUDENCE E. TAYLOR ©

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfilment of the requirements of the degree of MASTER OF NURSING

FACULTY OF NURSING

EDMONTON, ALBERTA

SPRING 1995

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FACULTY OF GRADUATE STUDIES AND RESEARCH

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DATE: 26 January 1995

To

Geoffrey, Duncan and Alexandra

ABSTRACT

In this study, the characteristics of a potential donor pool and the effectiveness of organ utilization were examined. The study was carried out in a multiorgan transplant hospital in Canada. A descriptive design was used in which a retrospective audit of the health care records was carried out for those patients less than 80 years of age who died in the Emergency Room or Intensive Care Unit (ICU) over a one year period.

There were 85 potential donors identified, 40 of whom were diagnosed brain dead and 32 met the medical criteria for donation. There were 19 effective donors. Familial consent was denied in eight cases. The remaining five cases were lost for separate reasons, however, there was only one case where donation was not considered. Of the 11 patients between 70 and 79 years, six met brain death criteria and two met the medical criteria for donation.

The findings from this study suggest that donor recognition is occurring and there is a small possibility of increasing the donor pool by using donors up to age 79 years. The donor procurement efficiency rating was 59.37%. The donor organ efficiency rating was; for kidneys 91.67%,livers 77.78%, hearts 52.63% and lungs 11.11%. When donated organs were not utilized it was mainly because of abnormal organ function and no suitable recipient match. The adult donor was most likely 39 years having died of a non-traumatic intracerebral event. The greatest potential for increasing the donor pool would be

through utilizing non-heart beating donors. Further research is suggested to determine the feasibility of a non-heart beating donor program, ICU nurses and donor families understanding of the donation process and native peoples understanding and the cultural meaning to them of organ donation and transplantation.

ACKNOWLEDGEMENTS

I acknowledge the valued support of my thesis committee. To Dr. Peggy Anne Field for her guidance, insight and understanding and to Dr. Marion Allen for reading, listening and for her support and encouragement. To Dr. Herb Northcott for his vision and fresh perspectives and to Dr. Norman Kneteman, for his interest and valued suggestions and comments throughout this project.

To my peers, the HOPE Coordinators, Anne, Shelly and Kim for their input and suggestions and to Maureen for her patience and the endless hours spent typing the manuscript. I would also like to acknowledge the generous financial support of the Kidney Foundation of Canada.

And finally, I wish to acknowledge the organ donors and their families, the true heroes of organ transplantation, for without them many lives would be lost.

TABLE OF CONTENTS

I. INTRODUCTION 1

Statement of the Problem 7
Purpose of the Study 8
Definition of Terms 9
Potential Organ Donor 9
Potential Donor Pool 9
Effective Donor 9
Brain Dead Patient 9
Organ Donor 9

II. LITERATURE REVIEW 11

Potential Donor Pool 11
Donors Per Million Population 11
Efficiency Rating 16
Definitions and Terminology 18
Factors Affecting the Characteristics of a Potential Donor Pool 20
Brain Death 20
Hemodynamic Instability 24
Medical Contraindications 25
Non-Utilization of Organs 25
Donor Age 27
Race 29
Consent 31
Summary 33

III. METHODS 35

Research Design and Description of the Sample 35
Population 36
Purposive Sampling 36
Data Collection 37
Instrument 37
Audit of Health Care Record 38
Data Analysis 39
Ethical Considerations 40

IV. RESULTS 42

Description of the Sample 42
Potential Donor Pool 44
Age 52
Brain Death 53
Cause of Death 57
Consent 57
Summary 60

V. DISCUSSION AND CONCLUSIONS 64

Discussion of Findings 64

Potential Donor Pool 64
Efficiency 65
Intensive Care Unit and Emergency Room Clusters . 66
Non-Brain Dead Groups 67
Brain Death 69
Consent 71
Effective Donors 72
Age 72
Efficiency of Organ Donation 72
Implications for the Major Study 73
Limitations of the Study 73
Implications For Nursing 74
Nursing Research 75
Conclusion 76

References 79

Appendix A: Purpose of Major Study 88
Appendix B: Data Collection Tool 89
Appendix C: Potential Organ Donors Code Sheet . . . 92
Appendix D: A Description of the Non-Brain Dead Cardiac Arrest Group 96
Appendix E: A Description of the Non-Brain Dead Treatment Withdrawn Group 97
Appendix F: A Description of the Brain Dead Non-Donor Group 98
Appendix G: A Description of the Brain Dead Effective Donor Group 99

LIST OF TABLES

Table	Description	Page
4.1	A description of potential and effective donors for audited deaths by emergency room cluster	44
4.2	The characteristics of the non-brain dead cardiac arrest group	46
4.3	Contraindications for organ donation in the non-brain dead treatment withdrawn group	47
4.4	Summary of those meeting brain death criteria for organ donation	48
4.5	Donor organ efficiency rating (DOER) by organ type	50
4.6	Characteristics of a potential donor pool by patient's age	53
4.7	Time between cerebral event and first declaration of those that met the criteria for organ donation	54
4.8	Pre-morbid diagnosis for the non-brain dead and brain-dead groups	57
4.9	Characteristics of potential donors where familial consent was denied	58
4.10	Health care professionals obtaining consent by sex of consenting family member	60

LIST OF FIGURES

Figure	Description	Page
4.1	The audit flow chart summarizing the sample	43
4.2	Reasons for non-organ utilization by organ type . . .	51
4.3	Waiting time between clinical examinations.	56

I. INTRODUCTION

Advances in the technology of organ transplantation has enabled hundreds of people with end stage organ failure to return to productive lifestyles. In Canada, both patient and graft survival are reported to be above 70% at one year for most organ groups (CORR, 1992). These improved outcomes have led to the development of an increasing number and diversity of transplant programs and an increasing number of persons being considered as transplant candidates. Furthermore, with fewer restrictions on the criteria for patient selection and greater public acceptance of transplantation as a therapeutic option, there are now lengthy waiting lists of those needing transplants. Therefore, the demand for donor organs has escalated to the point where the need far exceeds the supply. The quandary around how to increase the supply of cadaveric organs is a pressing issue based on the belief that there are many organs being wasted. New legislation and financial incentives are being considered with little acknowledgement and appreciation of the underlying factors affecting donor availability.

To facilitate organ donation in Canada, the Human Tissue Gift Act (1980) was legislated. This Act legalized the removal of organs from a certified brain dead person and endorsed a system for organ donation based on the voluntary altruistic motives of the donor's family. As more patients were being considered for organ transplants, it was realized

that further strategies to bridge the gap between the supply and demand for transplantable organs was required. Ontario and Alberta attempted to find answers for the emerging shortage of organ donors through Ministry of Health task force investigations which were conducted in the early 1980's. The findings of both groups suggested that there were many potential donors being lost (Alberta, 1985). In 1981, of the estimated 1200 potential donors in Ontario, only 110 became actual donors, a conversion rate of approximately 10%. It was estimated that between 45 and 80% of the total estimated donor pool were not being identified (Abbott, Keown, & Stiller, 1987). In order to convert potential donors into actual donors, the Ontario Task Force proposed recommendations focused on changing legislation, public attitudes, the organ retrieval system, and the medical system (Ontario Task Force, 1985).

Similar anatomical gift legislation with the commitment to donation by voluntary altruistic motivation was introduced into the United States as early as 1968. Then two further legislative efforts to improve donation were initiated. The National Organ Transplant Act in 1984 empowered the establishment of an organ procurement and transplant network and a registry of recipients. Then, the Omnibus Budget Reconciliation Act in 1986 led to the establishment of required request legislation which was enacted in 1987 (Stoeckle, 1993). This resulted in required request

legislation becoming a condition of Medicare and Medicaid reimbursement. It requires hospitals to establish written guidelines to ensure that the next-of-kin of potential organ donors were approached (DeLong, 1989). This legislation, also referred to as routine request or routine inquiry is still based on a system of voluntary altruistic consent by the potential donor's family. The premise of required request being that if approached for organ donation the family will consent and therefore more organs will be available (O'Connell, 1991). The result of this legislative change saw an increase in organ donation in some States, while in others there was no increase or, in fact, a decline in the donation rate (DeLong, 1989). Suggested reasons for the disappointing response to required request legislation have been: poor compliance, lack of knowledge about the organ donation process, and poor interpersonal skills by those approaching a family with great emotional needs at the time of acute grief (Stoeckle, 1993).

Several European countries have introduced another type of legislation known as presumed consent. This legislation empowers physicians to proceed with organ recovery without seeking permission from the donor's family unless the deceased had previously registered a wish prohibiting organ donation. The underlying premise of this legislation being that the family will no longer have to bear the *burden* of donation (Spital, 1991). In some jurisdictions where presumed consent

legislation was enacted, the family are asked if they would object to donation and their wishes are respected. Asking families about their objection, rather than their willingness to consider organ donation, is also thought to be more psychologically manageable for those approaching the families (Stoeckle, 1993). Some ethicists have challenged the moral and pragmatic implications associated with presumed consent, especially where the assumption of consent could be demonstrated as being false in many cases (Veatch, 1991).

Initially, countries such as Belgium and Austria, reported a significant increase in the number of donors following the introduction of presumed consent legislation (Roels & Michielsen, 1991). However, Austria reported a significant drop in the donation rate a few years later, which has led some to believe that the increase in donation was not attributed to the new legislation alone. Promotional activities directed at both the public and health care professionals prior to and during the early stages of enactment of the legislation were thought to have had a major impact on the donor rates. It was found that a decline in the intense level of educational and awareness activities was also associated with a decline in the donation rate (Wamser et al., 1993).

As a solution to the shortage of donor organs, there is some interest in having presumed consent legislation introduced into both Canada and the United States. Some

critics believe presumed consent is coercive and autocratic and that such legislation could potentially destroy a system that values voluntary donation and altruism as its foundation (Stoeckle, 1993).

The frustration towards the shortage of organ donors is also reflected in appeals to increase donation through incentives rather than the altruistic approach. Financial and non-financial compensation to donors, their estate or their families has been proposed (Kittur, Hogan, Thukral, McGaw, & Alexander, 1991; Stiller & Abbot, 1993). The controversy over incentives concerns the ethical implications of coercion and property rights of the human body (Cate, 1990).

Public opinion does not appear to be the major impediment to organ donation and the reason for the shortage of donor organs. Public surveys have repeatedly shown that the public are well aware of the need for donor organs and there is an expressed willingness to consent to donating the organs of a family member following death (Manninen & Evans, 1985; Walker et al., 1990).

The driving force to change legislation is the belief that there is public support for organ donation but many donors are lost because of an unwillingness to approach families. It is also presumed that many potential donors are not being recognized at the time of death. These presumptions are based on earlier studies where it was believed that there were sufficient organs to meet the needs of those needing

transplants (Abbott, Keown, & Stiller, 1987; Bart, Macon, Whittier, Baldwin, & Blount, 1981). There is now some thought that these earlier estimates of the potential availability of organ donors are too high, and, in fact, there is not a *paradox of shortage in the face of plenty* (Bart et al., 1981; Evans, Orians, & Ascher, 1992).

Other factors such as: a decline in trauma deaths, inadequate resuscitation following brain death, practices surrounding brain death certification, medical contraindications for donor acceptance and variances in acceptance of organs due to transplant programs' criteria and specific recipient needs have received little attention in explaining why some transplant programs recover more organs than others. Therefore, before programs consider introducing legislation and other incentives aimed at increasing organ donation, there needs to be some understanding of the real issues surrounding the characteristics of potential donors and efficiencies of organ utilization within a regional donor pool.

Nurses working in the area of transplantation are involved throughout the transplant process by caring for: the dying patient, the patient's family and the recipient and their family. In order to meet the needs of these individuals it is important for nurses to understand the transplant process and in particular to identify factors contributing to the shortage of organ donors. Based on an analysis of these

factors they can then make appropriate recommendations for changes in practice aimed at increasing the availability of donor organs. Hence, a study identifying a potential donor pool, describing the characteristics of this donor pool and effectiveness of organ utilization serves as a vital first step in understanding the organ shortage.

Statement of the Problem

The severe shortage of organ donors is the central limiting factor to the growth of organ transplantation as a successful rehabilitative procedure for those with many forms of end stage organ failure (Norris, 1990). While multifaceted and complex medical and social factors contributing to the donor shortage have been examined (Bodenham, Berridge, & Park, 1989; Bidigare & Oermann, 1991; Callender et al., 1991; Kennedy, West, Kelly, & Brotman, 1992; Silversides, 1992), only a few researchers (eg. Gore, Cable, & Holland, 1992; Evans, Orians, & Ascher, 1992) have sought to define the size and describe the characteristics of a potential donor pool as the first step to understanding the problems relating to the shortage of donor organs. It is suggested that changing public laws and policies without some knowledge of the characteristics of a regional potential donor pool may not necessarily result in more available organs for transplantation. Major regional differences in both size of the potential donor pools and the complexity of factors that compromise organ recovery from the brain dead patient have

been described (Gore, Cable, & Holland, 1992). Hence, if nurses involved in transplantation are to respond appropriately to the organ shortage, there is a need for them to know the prevalence of potential donors and to understand the factors that either impede or contribute to effective organ utilization within their donor referral base.

Purpose of the Study

The purpose of this study was to identify the potential donor pool in a tertiary care multiorgan transplant hospital in the Edmonton region and describe the characteristics of this pool and measure the effectiveness of organ utilization over a one year period. This study has preceded a major study which will describe the characteristics of a regional donor pool and measure the effectiveness of organ utilization over a three year period. The purpose of the major study is outlined in Appendix A. This study was used to refine the data collection tool and analysis plan that will be used in the major study. The specific research questions that arose out of the purpose for this study were:

- How many people who die in hospital emergency rooms and intensive care units are potential organ donors?
- What factors (eg. age, race, pre-morbid diagnosis, the ability to meet brain death criteria, the timing between the brain death declarations and organ recovery and time from the cerebral event to organ recovery and consent practices), affect the

availability of organs from a brain dead patient?

- What factors (eg. underlying infectious process, hemodynamic instability, abnormal laboratory findings, direct organ injury, non-utilization of healthy organs by transplant programs due to recipient specific criteria or program logistics) restrict the efficiency of organ utilization from an effective organ donor?

Definition of Terms

Potential Organ Donor: A potential organ donor is someone who has had a catastrophic cerebral event of known cause resulting in potential brain death. However, brain death may or may not have been declared and effective utilization of organs may or may not have occurred.

Potential Donor Pool: A potential donor pool is the aggregate of potential donors.

Effective Donor: An effective donor is where one or more organs were recovered and were effectively transplanted.

Brain Dead Patient: A brain dead patient is a deceased person who has no perfusion to the whole brain including the brain stem and has been declared brain dead but remains on a respirator and has an intact cardiovascular system which temporarily sustains viable organ function.

Organ Donor: An organ donor is a brain dead patient who can potentially be a donor of perfusable organs which includes lungs, heart, liver, and kidneys, but not

corneas, bone, or skin.

II. LITERATURE REVIEW

The purpose in this section is to review the literature related to the size and characteristics of organ donor pools and the effectiveness of organ utilization. Following a discussion on the potential supply of organ donors, issues are raised with regards to making international comparisons of donor pools and the methods used to calculate the estimated size of a potential donor pool. An explanation of the definitions and terminology used when analyzing a potential donor pool, is followed by a discussion on factors affecting the characteristics of a potential donor pool. These include factors relating to the diagnostic process of brain death; the effects of hemodynamic instability on organ utilization and reasons for organ non-utilization. Known medical contraindications for accepting donors or specific organs are outlined. Then, observed changes in the donor population with particular attention to the age and pre-morbid diagnosis and donation amongst minority populations are discussed. Finally, practices and issues surrounding consent are outlined and will conclude the literature review.

Potential Donor Pool

Donors Per Million Population

Since 1990, the number of organ donors in Canada has decreased. This, in part, is attributed to improved road safety and advances in the treatment of cerebral aneurysms (Silversides, 1990). While the size of the Canadian potential

donor pool is unknown, the donation rate is reported to be 12.6 donors per million population, with regional variances from 9.6 to 15.3 donors per million population (B. C. Transplant, 1992). This is fewer than the 17 donors per million population reported in the United States (Evans et al., 1992), and 14.6 and 42 donors per million population for the United Kingdom and Austria respectively (Feest et al., 1990; Wamser et al., 1993).

Using international comparisons to benchmark potential donor rates per million population have raised a number of questions. Some (eg. Gore, Cable, & Holland, 1992) have attributed the differences in reported donor rates to major variances in both program criteria for donor acceptance (the more restrictive the criteria, the fewer the numbers of potential donors) and the incidence of fatal head injuries and other cerebral events that result in brain death between geographic regions. Others (eg. Gentleman, Easton, & Jennet, 1990) have expressed concern for the validity in making such comparisons in the absence of standard definitions or standard criteria for identifying a potential donor and a potential donor pool. Evans, Orians, & Ascher (1992) derived their estimates for the supply of potential donors, regionally and nationally using reported mortality data. Apart from being concerned over the lack of uniformity in the application of codes and possible errors in the medical certification component of the death certificate, they agreed that this type

of analysis did not allow them to establish an actual number of potential donors at any level, only a range based on weak and strong possibilities that the deceased may have been a potential donor. However, they were able to show marked variances in the characteristics of the donor population and the numbers of potential donors across geographic regions and recommended that it was inappropriate to generalize estimates of the size of a potential donor pool based on small regional studies.

While Evans, Orians, & Ascher (1992) estimated the Pennsylvania potential donor pool to be between 21.8 and 34.3 donors per million population, an audit of health care records in that region indicated the potential donor pool to be between 38.3 and 55.2 donors per million population (Nathan et al., 1991). The lower number was based on a more restrictive estimate where brain death had been confirmed and a high probability for medical acceptance was evident. The higher number reflected a more liberal estimation based on assumptions that brain death was a potential diagnosis and all donors were medically acceptable. Although conducted at different times, other factors such as the different methods used to obtain data may have contributed to the variance found between these two studies. It is possible that the chart audit system allowed for a more accurate assessment of a potential donor than the medical certificate of death. A similar pattern of findings were reported in a study of a

potential donor pool in the Kentucky region. Garrison et al. (1991) also obtained their data through a chart audit and estimated this potential donor pool to be 50.8 donors per million population, while Evans et al. (1992) reported 23.4 to 40.0 donors per million population for the same region.

The characteristics and size of a potential donor pool are in part reflective of different research designs. Different study objectives, units of analysis, and data collection tools result in different conclusions that make comparisons between donor pools difficult and potentially meaningless. Although potential donors per million population have become the standard for measuring the size of a potential donor pool, the use of this standard has been questioned. Because donor rates are usually based on small area statistics where regional variations prevail, it has been suggested that alternative measures for estimating the size of a potential donor pool and in reporting efficiencies in organ donation are required (Gore, Cable, & Holland, 1992). Two alternative measures have been suggested by Gore, Cable, & Holland (1992). They propose that it would be more appropriate to measure organ donor rates either per 100 deaths per intensive care unit or per 100 cases where brain death was confirmed. This smaller denominator may make predictions of the size of potential donor pools and donor rates more meaningful as benchmark goals for local regions because it allows for regional variation in the type of patient admitted to an ICU

(i.e. clinical diagnosis and the incidence of events leading to cerebral versus extra-cerebral death) and severity of illness accommodated by various levels of ICU's (Gore, Cable, & Holland, 1992). This mode of analysis would not take into consideration a number of potential or missed donors. Such cases would include potential donors who died in the emergency room or in the ICU following cardiac arrest or the withdrawal of treatment where brain death diagnosis has not occurred (Salih et al., 1991).

There are new clinical interventions being employed to maximize organ donation. These raise the question as to whether donor pools should be classified according to whether the donor is either heart beating or non-heart beating and according to the strategies employed to optimize donation. Feest et al. (1990), have developed a protocol for admitting patients who have suffered severe cerebrovascular accidents to the ICU for elective ventilation. The purpose being that opportunities for donation are not lost when inevitable death is managed in this way. Another two interventions enable organs to be successfully recovered from the non-heart beating donor. The first involves a rapid core cooling procedure where an attempt is made to preserve organ integrity until the family can be contacted (Anaise et al., 1990). This practice has been successful in allowing young previously healthy individuals who die in the emergency room usually as a result of a traumatic event to become donors.

The second intervention involves the elective withdrawal of ventilation and inotropic support in the operating room and when death is declared organ recovery proceeds (Orloff et al., 1994). These selective patients would be those that do not meet brain death criteria yet death was inevitable.

The number of potential donors has also been reported in relation to organ specific criteria such as kidney donors per million population. Age is a particular criterion marker for most organ types. While fewer children less than two years of age would be considered kidney donors, not many adults over 55 years of age would be considered as heart donors. Therefore, the reporting of potential donors by organ group would not provide an inclusive estimate of the total regional donor pool but could be helpful to specific transplant programs by providing more focused information regarding the availability of specific organs (Gore, Cable, & Holland, 1991).

Efficiency Rating

While there is documentation on the numbers of actual organ donors, estimates of the potential supply of organs remains highly suspect (Evans, Orians, & Ascher, 1992). The numbers of actual donors is often used as the focus of performance and efficiency of the procurement programs across different geographic regions (Evans, Orians, & Ascher, 1992; The Coordinator, 1993). The problem with this type of analysis is that there is no consideration for regional

differences in the size of a potential donor pool or the efficiency of organ utilization in relation to actual donors.

The concept of efficiency is poorly defined with regard to donor recognition and organ utilization. In organizations concerned with total quality management, a measure of efficiency provides an outcome measure that corresponds to a program's performance. The effective utilization of organs from a recognized donor and the turning of a potential donor into an effective donor can be analyzed in terms of an efficiency rating (Evans, Orians, & Ascher, 1992). Efficiency has been expressed as a donor procurement efficiency rating (DPER). Evans et al. (1992) defined efficiency as the percentage of potential donors who become actual donors when measured across geographic boundaries. Efficiency ratings would provide more meaningful information on a transplant region's organ recovery performance than actual donors per million population. Measures of efficiency would accommodate regional variation in potential donors as well as identify those regions where organ recovery efforts are low. Furthermore, yearly variances in the availability of potential donors would not affect a program's efficiency rating. The effectiveness of organ utilization from an individual donor could also be expressed as a donor organ efficiency rating (DOER). The DPER and DOER could provide a mechanism for annual surveillance of a region's donor activity.

Definitions and Terminology

Differences in the definitions used to describe a potential donor pool and an actual donor have contributed to the uncertainty and confusion when comparing the potential availability of transplantable organs among regions. Gentleman, Easton, & Jennett (1990) propose that the reason more patients who die in an ICU do not become donors is because the bigger question of how a potential donor is defined remains ambiguous.

Although there are really only three absolute contraindications to donation: infection, cancer, and high risk social behaviour; there are many other conditions that are not universally applied which leads to program specific variances in the acceptance criteria. These are often referred to as marginal donors because there is some reversible or minimal organ dysfunction which may be a result of normal aging, trauma, or other systemic diseases. However, when such small numbers are being used in calculating program activity, the acceptance of such donors in one program versus another becomes problematic (Wheeldon, Potter, Jonas, Wallwork, & Large, 1993). Conservative, intermediate, liberal, Class I and Class II donors, are some of the terms used to differentiate between a strong and weak estimate of the potential for a patient to be diagnosed brain dead and for the brain dead patient to become a donor (Evans et al., 1992; Nathan et al., 1991). The application and interpretation of

these terms when making comparisons among potential donor pools creates a number of problems especially in relation to what is really being compared with what. While the conservative approach would have the potential of eliminating some potential donors the liberal or Class II approach clearly over estimates the size of a potential donor pool. Liberal estimates have often included patients that have not fulfilled the criteria for brain death and therefore, these cases would never have been considered as organ donors. The inclusion of these cases when defining a potential donor pool not only weakens the validity of the data but also leads to the misinterpretation of the results. This may lead to unrealistic expectations of transplant programs of the potential availability of organs and administrative expenses related to new policy and legislative development designed in response to the believed shortfall in actual donors.

There are often cases where a donor may be referred to the procurement program having met brain death criteria and familial consent obtained but organs are never recovered. While these donors have certainly been recognized, it is unclear how they have been classified among regions.

The term effective donor has been used to describe cases where donor criteria were met and organ recovery or extraction has occurred (Navarro, Escalante, & Andres, 1993). It is unclear if cases where organs are recovered but not transplanted are also included in this definition of a donor.

The reasons why organs are not transplanted following recovery vary. The most frequently reported reasons are: abnormal pathophysiology, hemodynamic instability resulting in long periods of hypotension or high doses of vasoactive drugs that may have compromised organ function or non-utilization by the transplant programs. The latter is most often due to either administrative logistics such as shortage of staff to take care of the recipient post-transplant to no longer having a suitable recipient match (Gore, Cable, & Holland, 1992; Gore, 1991; Gore, Taylor, & Wallwork, 1991).

Factors Affecting the Characteristics of a Potential Donor Pool

Audits of health care records have been undertaken to not only determine the number of potential donors, but also to look at a number of factors that may contribute to regional variation in both actual and potential effective donor utilization rates. Age, race, brain death, consent, medical management, medical contraindications and restrictive program criteria are some of the factors that have been identified.

Brain Death

Confirmed brain death which is equivalent to death, is a mandatory pre-requisite for cadaveric organ donation. The clinical criteria for diagnosing brain death was first reported by Harvard Medical School in 1968 and since that time there has been little variation in the neurological criteria that must be met in the presence of a known cause of coma

(Norton et al., 1990). The clinical criteria for diagnosing brain death was first developed from studies on adults and the same criteria are now being applied to children and infants with some modifications in the timing between the two clinical examinations and the use of supplementary diagnostic tests (Norton et al., 1990). The understanding of brain death in the infant and small child is still unfolding. Consequently, the absence of clear guidelines which specifically identify the declaration process, recognizing infants' resilience to developing brain death, may effect the willingness of physicians to become involved with donation in this group of potential donors (Norton et al., 1990). Furthermore, the required two declarations to confirm the diagnosis of brain death is time consuming and has been thought to increase the emotional burden for families and the staff in the ICU.

The waiting period between the two declaration examinations varies among centres. In a study looking at the practices of determining brain death, Norton et al. (1990) found in 42% of the cases, the time between clinical exams was zero to six hours and in 21%, 13 to 24 hours and in 37% of the cases, seven to 24 hours. British criteria emphasize the need to satisfy the preconditions before testing but do not specify an interval between tests. Less than one hour between the clinical tests was reported by one group in Britain (Gentleman, Easton, & Jennett, 1990). The Canadian guidelines state that the preconditions must persist when the patient is

reassessed after a suitable interval which may be as short as two hours or up to 24 hours in cases due to anoxia or ischemia (Canadian Congress of Neurological Sciences, 1987).

While clinical testing allows for the diagnosis of brain death to be made at the bedside and can be undertaken as soon as it is felt that the patient will meet the criteria, at times confirmatory or supplementary testing is undertaken to determine cerebral blood flow or electrical activity. The types of confirmatory tests used are electroencephalogram, cerebral angiography, and radionuclide scintigraphy. These tests may be necessary because of the nature of a patient's injuries or because of preferences by physicians or hospitals to do this. Because these tests require the participation of clinicians from outside the patient care unit, there is the potential for delays in diagnosing brain death (Norton et al., 1990). Norton et al. (1990) found clinical criteria alone was used in 67% of brain death declarations and confirmatory testing was variably restricted for use on non-trauma patients and those hospitalized for greater than five days.

Regional variation in cases where brain death is not a possible diagnosis may reflect patient referral practices and trauma centre location (Gore, Cable, & Holland, 1992). While the potential for brain death diagnosis is thought to be around 22 to 26% of all ICU deaths for an ICU that receives neurology and trauma patients, the actual number of patients that meet the criteria is reported to be significantly less

(Gore, Cable, & Holland, 1992; Gentleman et al., 1990). A number of missed opportunities for undertaking brain death testing have also been found. Some of the reasons for this have included resource restraints in the ICU, indifferent attitudes towards transplantation, asystole occurring before the declarations were undertaken, physician not identifying the potential donor or inaccurately ruling out the possibility for donation and concern for families who had already gone through enough stress (Gentleman et al., 1990; Garrison et al., 1991).

Some potential donors are lost before brain death testing is undertaken, while others have reported that 10% of potential donors develop asystole during the process of declaration (Hammond, 1992). Furthermore, an increase in asystole has been noticed when the time between the two diagnostic tests is greater than 12 hours (Gentleman, Easton, & Jennett, 1990; Kennedy et al., 1992). Other factors that affect the successful outcome of organ recovery during this time are: the length of time from the initial cerebral event to the patient becoming brain dead, management issues such as failure to correct acid base imbalance following the initial testing, or impaired tissue perfusion. Delays in undertaking the declaration are thought to result in prolonged hemodynamic instability due to hypovolemia. Furthermore, delays may be associated with an increased risk of donor sepsis (Norton et al., 1990).

Hemodynamic Instability

The clinical management of the organ donor consists of intervening in the course of somatic death in order to maintain organ function. This process can only be sustained for a limited time before hemodynamic collapse occurs. Donor hemodynamic instability is seen as a major reason why organs are not utilized. Bodenham, Berridge, & Park (1989) found poor hemodynamic performance the reason 25% of potential donors did not proceed to donation. The brain dead patient is a new category of patient who presents many management challenges that must be sustained over a number of hours until serology screening is completed and transplant teams are assembled (Powner, Jastremski, & Lagler, 1989). The goal of normal tissue oxygenation and optimal tissue perfusion are no different than in the management of any critically ill patient (Kappel, 1993).

Because potential donor identification may start in the Emergency Room, the auditing of deaths in this area is also important. Cardiopulmonary arrest, hypotension, and hypoxemia are reasons many donors are lost, many within the first few hours of arriving in hospital (Kennedy et al., 1992; Gore, Cable, & Holland, 1992). Maximal resuscitative efforts in the Emergency Room can lead to more potential donors and a better quality of organs offered for transplantation (Garrison et al., 1991; Dominguez-Roldan, Murillo-Cabezas, Munoz-Sanchez & Gonzalez-Menendez, 1992).

Medical Contraindications

Medical contraindications to either donor acceptance or acceptance of specific organs is another factor that affects both the potential donor pool and specific organ utilization. General criteria for excluding a potential donor include underlying infectious diseases and extra-cranial malignancy, high risk lifestyle practices such as intravenous drug abuse, prostitution and homosexual behaviours, and unknown cause of coma. Also, organs may be excluded because of injury and underlying disease processes affecting organ function such as diabetes mellitus (Kappel, 1993). Gore, Cable, & Holland (1992) reported 17.5% of the potential donors who met brain death criteria were excluded for donation because of medical contraindications. At times, medical contraindications may reflect specific program restrictions or those of the potential transplant candidate. It is for this reason that optimal organ utilization is contingent on the access to a large and diverse pool of potential transplant candidates. In order to understand organ utilization rates, the incidence of factors that contradict and impede organ utilization need to be identified.

Non-Utilization of Organs

While transplant programs have expressed concern over the shortfall of organ donors, they have shown little attention to the number of organs not utilized because of program logistics. While the reasons transplant programs decline to

use a specific organ varies, some common reasons for declining are: restrictions in program specific organ acceptance criteria, distance between the donor and recipient centre (therefore prolonged organ ischemic time), resource restraints at the transplant centre and recipient/donor mismatch (Usually due to incompatible blood group or size) (Evans et al., 1992; Gentleman, Easton, & Jennett, 1990; Gore, Taylor, & Wallwork, 1991; Gore, Cable, & Holland, 1992). Gore, Taylor, & Wallwork (1991) found that while non-utilization of offered kidneys was rare about 13% of suitable hearts and 30% of suitable livers and lungs were not recovered.

Reliability of judgement for ascertained organ suitability is difficult to assess especially as donor acceptance criteria varies and is often in response to urgent patient needs. Organ suitability is an expanding field of research. Expanding the donor pool to include *marginal donors* raises some questions regarding the efficacy of transplanting organs where there is evidence of compromised function or where donor criteria is associated with compromised outcomes in the recipient (Boehmer, 1993; Gruenberger, Sautner, Wamser, Mittlböck, & Mühlbacher, 1993).

While there is an increasing interest in measuring the outcomes of recipients of organs from the *marginal donor*, there is minimal interest in increasing the donor pool by improving the function of the initially hemodynamically unsuitable organ donor. The few case control studies that have been reported

suggest that there is a potential for increasing the heart donor pool up to 30% and significantly improving the function of *marginal* hearts using hormone replacement therapy (Novitzky, Cooper, & Reichart, 1987; Wheeldon, Potter, Jonas, Wallwork, & Large, 1993).

The recent recession has led to hardships and an increased awareness of health care costs. While transplant programs can debate the cost effectiveness of transplantation versus maintaining someone in end stage organ failure until death, organizational costs incurred as a result of multiorgan donor activities have received little attention. Administrative and public relations aspects surrounding the activities in the ICU and operating room may be detrimental to increasing organ donation. Inexperienced surgeons undertaking the organ recovery can lead to extended operating times leading to increased utilization of resources in the donor hospitals. Furthermore, the *hassle factor* associated with multiple transplant teams with specific requests may create a negative effect in donor hospitals where there is an increased demand for rationed resources (Feest et al., 1990; Slapak, 1993). Some speculate that such experiences lead to negative attitudes toward transplantation and effect the motivation of donor hospitals to become involved (Slapak, 1993; Wamser et al., 1993).

Donor Age

The age for donor acceptance is very much in accordance

with program acceptance criteria and the urgency of need by recipients. While it has been suggested that the age of donors has increased in response to the demand for more organs, there is a need to realistically determine the factors that limit the use of older donors (Boehmer, 1993; Orlowski & Spees, 1993). There has been an increase in the acceptance of older donors dying of subarachnoid hemorrhage which some believe is a response to the decline in trauma deaths which were on average comparatively younger (Orlowski & Spees, 1993). Orlowski and Spees (1993) found a direct correlation between the decrease of trauma deaths and the increasing age of the donor population. They reported that over a five year period the mean donor age increased from 26.09 years to 33.96 years. In the same time, the number of deaths attributed to trauma decreased from 67.7% to 47.1%. With the development of infant and pediatric heart, lung and liver transplant programs, there is now a great demand for all organs for all ages of recipients. Even though it has been shown that parental support for donating a child's organs is high, there remains a serious shortage of organs for small children (Walker et al., 1990).

While there has been successful outcomes for patients receiving organs from older heart, liver, and kidney donors, increased age is often associated with structural and functional changes (Pflugfelder et al., 1991; UNOS, 1993; Kumar et al., 1993). Studies of potential donor pools have

often omitted the newborn potential donor and those over 65 years of age. Where donor age has been extended, it has been found that a majority of the unrecognized potential donors have tended to be greater than 45 years (Nathan et al., 1992). More recent practice is to consider potential donors from full term infants up to 79 years of age inclusive. The effect of considering donors between 70 and 79 years of age could have positive results for increasing the potential donor pool. Out of a potential donor pool of 279 cases, Salih et al. (1991) report that 91 potential donors were between the ages of 70 and 79 years. It is realized that an over emphasis on age precludes the use of a number of suitable organs for transplantation; the challenge is to understand the various limits aging has on organ function in the transplanted organ.

Race

The incidence of some forms of end stage organ failure is greater amongst some minority groups in proportion to that group's representation in the population as a whole. Yet some data suggest that when approached for donation, non-white racial groups are less likely to consent to donation than whites (Garrison et al., 1991). While the practice of organ donation has not been supported by a number of ethnic groups because of religious and cultural indifference; many of those needing transplants are from minority groups. Immunogenic studies show that certain histocompatibility antigens occur with greater frequency in specific racial groups (Callender et

al., 1991). Therefore, because donor pools are largely made up of Caucasians, the ability for minority groups to receive a well matched organ becomes problematic (Stoeckle, 1993). Therefore, an increase in minority donors would provide for improved organ matches and graft survival amongst minority populations.

Sensitivity to various cultural mores and knowledge about culturally diverse communities is viewed as an important aspect when interacting with any specific cultural group and is thought to be an important factor when discussing organ donation (Green, 1993). The question as to whether it makes a difference if the race of the requester is the same as the donor family is receiving recent attention. The experience of one group (Harrington, 1993) would suggest that it does make a significant difference. Their program had minority coordinators educating minority communities about their cultural needs and were seen to be influential in improving organ donation rates in that community. Others (eg. Shapiro, 1992) have reported an increase of familial consent by 31% when a minority group is approached by someone of the same ethnic background. Exley, Lane, & Serbin (1993) suggest other hospital employees (eg. unit clerks) of the same ethnic group as the donor family be used to accompany the requester in order to bridge the gap between cultural and social differences of the requester and the family. Shortages in available donor organs is problematic for all groups, however,

some minorities encounter unique problems. By improving the relationships and understanding the uniqueness and needs between ethnic groups and the health care community; minority groups may be more receptive to organ donation and, therefore, have improved opportunities for successful transplantation (Stoeckle, 1993).

Consent

Practices surrounding consent have been recognized as major underlying factors affecting organ donation. Lack of physician willingness to discuss donation with the family, the timing of approaching the family regarding organ donation, the family members' willingness to consent dependent on their relationship to the deceased and the approval of the Medical Examiner are common themes throughout various studies. A number of these factors are region-specific and may be overcome by intervening with appropriate education strategies.

In most instances, families are approached by physicians with some suggestion that they are more successful than nurses in having the family agree to donation (Norris, 1990; Gentleman, Easton, & Jennett, 1990; Garrison et al., 1991). However, physicians have also been a major reason families were not approached most often due to concern for the families well-being or perceiving that the mention of donation to the family would add further grief. Business of the unit and personal unwillingness to participate in organ donation have also been reported as factors (Gore, Cable, & Holland, 1992).

The role of the transplant coordinator in obtaining consent is unclear. Some report that they play a role in the timing of the consent discussion and directing the flow of enquiry (Garrison et al., 1991; Kennedy et al., 1992).

The timing of the family discussion appears to be significant in obtaining a successful outcome. An increase in familial refusal has been reported when the request was made both prior to the explanation of brain death and before completion of the brain death criteria (Garrison et al., 1991; Kennedy et al., 1992).

Decoupling of the brain death discussion from the organ donation discussion also appears to be an important factor. A situation is considered decoupled when the family clearly indicates that they have understood and accepted brain death prior to any discussion on organ donation. This is described as a temporal separation which may occur during one or a number of interactions with the family. Whereas coupling is said to occur when there is no indication that the family have accepted brain death before there is a discussion on organ donation (Garrison et al., 1991). Garrison et al. (1991) found that when there was a clear temporal separation of the explanation of death and donation, the donor success rate was 53 out of 82 potential cases. In contrast, there were only 11 out of 61 successful outcomes when both the brain death and organ donation discussions were combined before there was evidence that the family had accepted brain death.

Denied familial consent is the major reason why identified potential donors do not progress to organ donation. Public opinion is a major factor in organ donation and recent studies show that not all people are supportive of it (Manninen & Evans, 1985; Walker et al., 1990). Findings for several studies show that refusal rates affect about 30% of the potential opportunities for donation, while some indicate a trend of increased refusal (Salih et al., 1991; Garrison et al., 1991; Gore, Cable, & Holland, 1992; Etienne et al., 1991).

Medical Examiners or Coroners have the authority to override the consenting families' wishes based on the need to rule out medical misadventure or where the injuries leading to brain death will result in serious criminal charges (Bodenham, Berridge, & Park, 1989). Results from some studies (Gore, Cable, & Holland, 1992; Garrison, Easton, & Jennett, 1990) have shown that Coroners' refusal to proceed with organ recovery accounts for the loss of 10 to 20% of potential donors.

Summary

In summary, the disparity between the demand for organs and the number of potential donors continues to increase. Reasons for the organ shortage are varied and have been attributed to a number of causes. Audits of health records allows procurement programs to identify not only the size of a Potential Donor Pool but also distinct characteristics of the

donor population in a specific donor region. Only then, can appropriate strategies to enhance opportunities for organ donation be identified. Furthermore, knowledge of the effectiveness of organ utilization will provide outcome measurements based on efficiencies. This will provide for more meaningful comparisons of donor activity and organ utilization practices within this transplant region.

III. METHODS

The purpose of this chapter is to describe the methods used in this research study. The research design and the final sample are first discussed. The data collection procedures are then outlined followed by an explanation of the data collection instrument and methods used for data analysis. The chapter concludes with a description of the ethical considerations specific to this study.

Research Design and Description of the Sample

A descriptive retrospective audit of the health care records was the design chosen to answer the research questions in this study. This design was thought to be appropriate (Brink & Wood, 1989) as the variable, a potential donor pool, was amenable to description. Furthermore, little was known about the characteristics of this donor pool and the effectiveness of organ utilization in this region, as this population had never been studied before. Previous research of potential donor pools does provide the rationale for transplant programs to undertake this type of study within their donor regions.

The setting for this study was a large tertiary care multiorgan transplant hospital in Edmonton, Alberta, Canada. All data were collected in the medical records department except for the secondary data concerning the effectiveness of organ utilization which were obtained from the organ donor

records in the office of the Human Organ Procurement and Exchange Program (HOPE).

Population

The population was considered to be all potential organ donors at this major hospital. The unit of analysis was the hospital health care record of patients who died in the emergency room and the intensive care units during the 12 month period.

Purposive Sampling

A four step purposive sampling procedure was used to obtain the sample.

Step 1 The hospital's Medical Records Department identified all patients less than 80 years of age who died in the emergency room or an intensive care unit from January 1st, 1993 up to and including December 31st, 1993. The health care records of these deceased patients were then made available to the researcher.

Step 2 Those records of infants weighing less than three kilograms were excluded.

Step 3 Those records indicating a pre-morbid diagnosis other than those listed in Section D of the data collection code sheet, Appendix C were excluded.

Step 4 Borderline cases were identified when a period of coma occurred prior to death, but the pre-morbid diagnosis was not clear. These cases were reviewed with the Director of the Human Organ Procurement and

Exchange Program to determine inclusion.

The remaining health care records were then audited to identify factors that would determine the deceased as a potential donor and factors that would contribute to effective organ utilization.

Missing health care records were identified using the master list generated by the health records analyst. A second request was made to the Medical Records Department to have these records pulled.

Secondary information was obtained from the HOPE Program organ donor records. The secretary of the program identified the records of all organ donors who were referred to the program from the emergency room or an intensive care unit in the hospital from January 1st, 1993 until December 31st, 1993. These records were audited to identify factors relating to the inability to recover organs and the efficiency of organ utilization.

Data Collection

Data collection was the responsibility of the investigator and it took place during a two and a half month period from July 1994 to mid-September 1994.

Instrument

All information was collected using the instrument designed by the investigator (see Appendix B). The items on the instrument were generated from factors identified in the literature as being related to the characteristics of an organ

donor pool and the effectiveness of organ utilization. Face and content validity of the data instrument were assessed by an expert panel composed of three organ procurement coordinators and a transplant physician. The panel also addressed content validity of the instrument as a whole by examining the relevance and representatives of all items on the instrument to address factors that would influence the identification of a potential donor pool and the effectiveness of organ utilization.

Members of the expert panel suggested the addition of two items to the tool. The first was an item to indicate if confirmatory brain testing was done and if so the indication for using confirmatory testing and the type of test chosen. The second item was to have 'other' added to the list of factors attributed to non-utilization of organs. These adjustments were made in agreement with the panel.

Reliability of the data were enhanced as the investigator is an experienced organ procurement coordinator with the HOPE Program and all data were collected by the investigator. The investigator was also familiar with the health care record used in the hospital and the procedures used for identifying a potential donor and declaration of brain death.

Audit of Health Care Record

Following the method outlined in the purposive sampling technique data were entered onto the instrument for all cases that met the criteria. The information was obtained from the

last admission where death was the final outcome. The pre-morbid diagnosis was obtained from either the autopsy report or the physicians discharge summary in those cases where an autopsy was not performed. The audit process was determined by both the type of information requested and the sequence that it appeared on the instrument. Where information was not found NA (Not Available) was entered. Only demographic information was collected on those that did not meet the criteria for inclusion in the study. The instrument enabled the researcher to identify the potential donor pool and the characteristics of the donors in the pool.

Data Analysis

The reporting of sample characteristics and frequency tabulations arising from the data were facilitated by using tables and graphs. Contingency tables and chi-square analysis were used when making comparisons between groups. The donor procurement efficiency rating (DPER) and the donor organ efficiency rating (DOER) were calculated for the number of effective organ donors and the number of organs utilized from a single donor. The DPER was reported as a percentage of the number of effective donors for all: audited deaths, potential donors, and those meeting both brain death and the medical criteria for donation. The DOER was reported as a percentage of the number of organs transplanted for the total number of potentially transplantable organs. The DOER was also reported for each organ type.

Ethical Considerations

Appropriate institutional and faculty ethical approvals were obtained before proceeding with the study. Written consent permitting access to the health care records was also obtained from the hospital administration. The hospital's participation in this study was voluntary and strategies to recognize and ensure confidentiality and protection of anonymity of all information contained in the health care record were taken. Furthermore, measures were taken to ensure that the Human Tissue Gift Act was not violated with regards to donor identity. All information was collected either in the research cubicles in the Medical Records Department or the HOPE office. The information was collected using the research tool designed by the investigator and patient names were not transcribed. The patient's hospital number on the health record was used to connect the hospital record with the HOPE donor record. Access to the data was limited to the investigator by virtue of the investigator personally undertaking all data collection and keeping the information in a locked filing system.

Specific patients were not identified when information was shared with the clinical expert or in the dissemination of the results as only grouped data are reported. However, where specific cases or data were identified, anonymity was protected by not revealing demographic information that would lead to the potential disclosure of the deceased.

Following final analysis of the data, all patient lists provided by the Medical Records Department were destroyed by the investigator. Data collection forms, letters of permission to access the health records, letter of support for the study along with the disk containing downloaded files will be kept for seven years after which all files will be destroyed. Following the downloading of computer files, all data and files stored on the hard drive were erased.

If further analysis of this data is planned by the researcher or others, further ethical board approval will be obtained.

IV. RESULTS

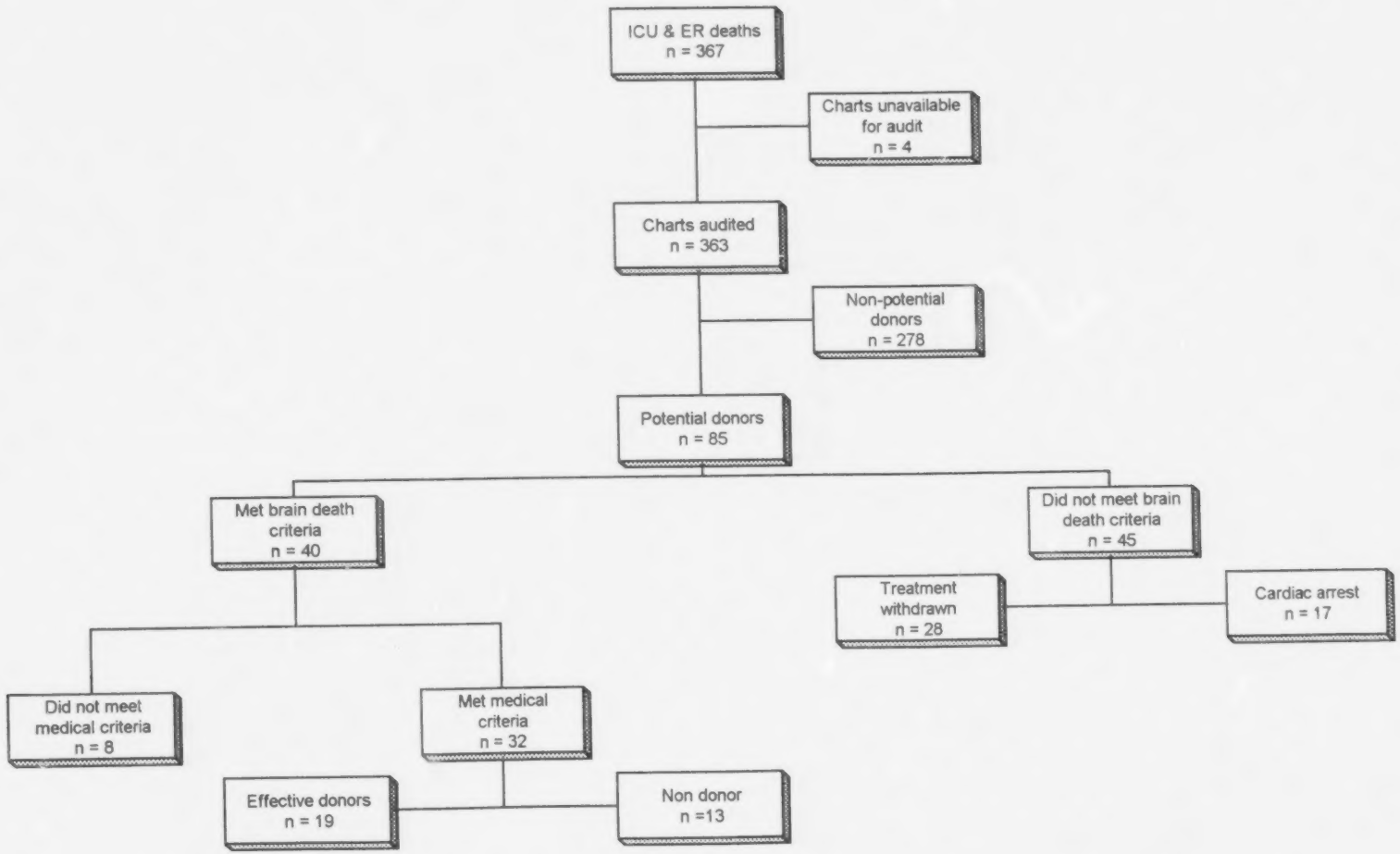
In this chapter, the findings from the study are described. Statistical analysis was done using Epi Info 5.01b - July 1991.

Description of the Sample

The Medical Records Department identified 367 patients less than 80 years of age who died in the emergency room or an intensive care unit (ICU) during the calendar year 1993. Figure 4.1 shows the audit flow chart summarizing the characteristics of the sample. Only four records were unavailable for review. The remaining 363 charts were audited providing 98.91% coverage. Of these, 278 were eliminated from further study based on the criteria outlined in the purposive sampling procedure. Two cases where the pre-morbid diagnosis was not listed on the code sheet and brain death was diagnosed were reviewed with the Director of the HOPE Program. A further classification, cerebral infarct, identified by code 014 was added to the code sheet. The remaining 85 cases were considered to make up the potential donor pool and were studied extensively.

Figure 4.1

The audit flow chart summarizing the sample



Potential Donor Pool

Table 4.1

A description of the potential and effective donors for audited deaths by emergency room and ICU cluster

Cluster	Audited Deaths (n=363)	Potential Donors (n=85)	Brain Dead (n=40)	Effective Donors (n=19)	% Effective Donors			
					Audited Deaths	Potential Donors	Brain Dead	Medical Criteria (n=32)
Emergency Room	80	13 (16.25%)	3 (3.75%)	0	0	0	0	0
Adult non-cardiac ICU	128	53 (40.77%)	31 (24.22%)	15	11.72	26.30	48.39	53.57
Adult cardiac ICU	86	6 (6.98%)	1 (1.16%)	0	0	0	0	0
Pediatric ICU	69	13 (18.84%)	5 (7.25%)	4	5.80	30.77	80.00	100.00
Total	363	85 (23.42%)	40 (11.02%)	19	5.23	22.35	47.50	59.37

Table 4.1 shows a description of the potential and effective donors for audited deaths by emergency room and ICU cluster. Of the 363 audited deaths, 23.42% were identified as potential donors. The adult non-cardiac cluster had significantly more potential donors per audited deaths (40.77%) than the pediatric (18.84%) and the cardiac (6.98%) clusters (x^2=34.24 P<.4x10^{-7}). The largest decrease in the donation process occurred in the step between potential donors (85) and those that met brain death criteria (40). Only 19 of those that met brain death criteria became effective organ donors.

The donor procurement efficiency rating (DPER) was 47.5% for those 40 patients that met brain death criteria and 59.37% for the 32 that met the medical criteria for organ donation. The DPER was 80.00% for the pediatric brain dead cluster compared to 48.39% for the adult non-cardiac brain dead

cluster.

Table 4.2

The characteristics of the non-brain dead cardiac arrest group

Site of Arrest	Frequency (n=17)	Mean time from cerebral event to cardiac death
Out of hospital	6	53 minutes
Emergency room	3	1 hour 53 minutes
Operating room	2 (1)	6 hours 53 minutes (120.00 hours*)
Intensive care unit	5	15 hours 40 minutes

* One patient died in the operating room having been in the ICU for five days

The 45 cases where brain death was not met were divided into two groups, those cases where cardiac arrest occurred (17) and those cases where treatment was withdrawn (28). Table 4.2 shows that of the cardiac arrest group, six patients arrested before reaching the hospital, however intensive resuscitative efforts continued in the emergency room where death was later pronounced. Another three patients arrested and died in the emergency room while a further two cases died in the operating room before arriving in the ICU. A third death also occurred in the operating room five days after being admitted to an ICU. These operating room cases were included in the study because they were considered to be an ICU patient at the time of death and were recorded as an ICU death. Of the remaining five patients who died in the ICU, three were between 60 and 69 years where the pre-morbid diagnosis was post-cardiac arrest cerebral hypoxia. The remaining two cases were children. The mean time from the

cerebral catastrophe to cardiac arrest was 53 minutes for the out of hospital group and 1 hour 53 minutes for the emergency room group. The mean time for the pediatric ICU cluster was 12 hours and the adult ICU cluster 18 hours. A description of the non-brain dead cardiac arrest group is shown in Appendix D.

Of the 28 cases where brain death criteria were not met before treatment was withdrawn, five patients were greater than 70 years of age and three were newborns. Treatment was withdrawn in the ICU in all but one case. In this situation, treatment was withdrawn in the emergency room because organ donation was said not to have been pursued because of advanced age (74 years). The time from the cerebral catastrophe to cardiac death in this case was seven hours, whereas the mean time for the group as a whole was 134 hours.

Table 4.3

Contraindications for organ donation in the non-brain dead treatment withdrawn group

Reason	**Frequency (n=13)**
Infection	8
Cancer	3
Intravenous Drug User	2

Table 4.3 shows that at the time treatment was withdrawn, 13 patients presented absolute contraindications for organ donation (infection, cancer, and high risk social behaviour).

Of these, eight had infections, three cancer and two were known intravenous drug users. A description of the non-brain dead treatment withdrawn group in shown in Appendix E.

Table 4.4

Summary of those meeting brain death criteria for organ donation

Stated Outcome	Frequency (n=40)	Met Medical Criteria (n=32)
Too old (>70 years)+	6 (15.0%)	0
Infection	1 (2.5%)	0
Prolonged hypotension++	1 (2.5%)	1
Cardiac arrest+++	1 (2.5%)	1
Prior arrangements to donate body to the Department of Anatomy	2 (5.0%)	1
Because of being an North American Indian	1 (2.5%)	1
Unable to locate next-of-kin	1 (2.5%)	1
Consent denied	7 (17.5%)	7
No reason	1 (2.5%)	1
Effective donor	19 (47.5%)	19

\+ Consent was also said to have been denied in two of these cases. One had significant multiorgan failure and one had normal liver function but impaired renal function.

++ Liver and renal function tests were within normal limits. Treatment was withdrawn.

+++ Cardiac arrest occurred following cerebral blood flow studies. Full resuscitation was not carried out.

The 40 cases where brain death occurred were also divided into two groups, the brain dead non donor group and the effective donor group. Table 4.4 shows the outcome of those meeting brain death criteria. Of these, eight disqualified for donation based on medical contraindications and acceptance criteria of age (for the purpose of this study the donor age for medical acceptance was assumed to be less than 70 years),

infection, and somatic death. In two cases, there were insufficient reasons for not pursuing organ donation. One case was not considered because prolonged hypotension had been assumed to have caused significant organ injury. However, there was no evidence of significant hepatic or renal malfunction that would have disqualified donation. In the other case, donation was thought to have been overlooked as no reason was found as to why donation was not considered. This patient had been hospitalized for six days prior to death. A full description of the potential donors who met brain death criteria is shown in Appendix F.

Of the 19 effective organ donors, 15 (78.95%) were multiorgan donors and four (21.10%) single organ donors (kidneys counted as one organ). In one case, a newborn, the heart was the only organ that was potentially transplantable therefore, the donor organ efficiency rating (DOER) in this case was 100%. While each of the remaining three cases identified impairment of some organs' functions, in all cases other organs were also lost because of no suitable recipients. In two cases recipient matching was not possible because of donor size (>112 kg) and the other case was a combination of size and blood group incompatibility (Group B).

Cardio-respiratory arrest occurred in three effective donors prior to becoming brain dead. In two cases the arrest occurred outside the hospital and in one of these the heart was transplanted. In the other, it was suitable; however, no

recipients were found because the donor was Hepatitis C positive. Of all those who arrested, the liver was able to be transplanted on two occasions and the kidneys in all three cases. There were five more cases where significant hypoxemia occurred following admission to the ICU. In four of these, it occurred during the apnea test where the arterial PaO_2 dropped below 30 mmHg for up to 10 minutes. Pre-oxygenation therapy did not appear to have occurred in any of these cases. In two situations, the arterial PaO_2 was less than 90 mmHg on an FiO_2 of 1 and 0.8 prior to the apnea testing. Of these five cases, five were kidney donors, four were liver donors and three were heart donors. There were no effective lung donors among those that had incurred a cardio-pulmonary arrest or significant hypoxic episode.

Table 4.5

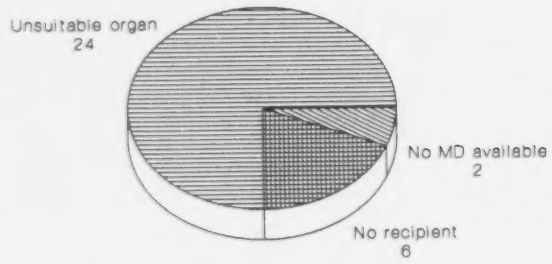
Donor organ efficiency rating (DOER) by organ type

Organ	Donors	Potential Organs	Transplanted	DOER
Lungs	18	36	4	11.11%
Heart	19	19	10	52.63%
Liver	18	18	14	77.78%
Kidney	18	36	33	91.67%

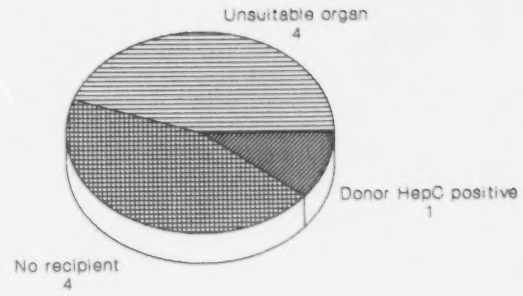
Organ specific efficiency ratings are shown in Table 4.5. The overall DOER was 59.95%. The highest DOER was found in the kidney group which had an efficiency rating of 91.67% and the lung group had the lowest rating at 11.11%. Figure 4.2 shows the reasons for non organ utilization by organ group.

Figure 4.2

Reason for non-organ utilization for each organ type



Lung



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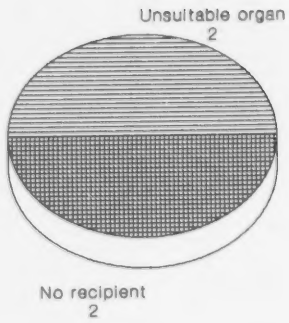
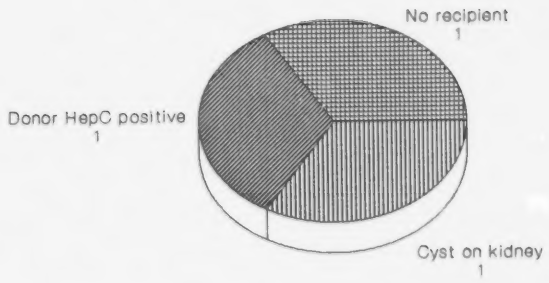


Liver



Kidney

Poor organ function was the most common reason for non-utilization, followed by no suitable recipient due to either size or blood group (two of the 19 donors were blood group AB and one pediatric donor was group B). Only three donors had a 100% efficiency rating with all organs being transplanted. The mean time from the cerebral event to vascular cross clamp was 43.5 hours and from brain death to vascular cross clamp 16 hours 8 minutes. On 16 occasions, vascular cross clamp occurred within 20 hours of the first brain death declaration which is the official time of death. A description of the brain dead effective donor group is shown in Appendix G.

Age

Of those who were identified as potential donors, 11 were aged 70-79 years of age and 74 were from birth to 69 years as shown in Table 4.6. Only in the age group 0-9 years where brain death was met (5 cases), 100% familial consent was achieved. Effective organ recovery did not occur in one case because the donor was felt to have unresolved infection. Children (<18 years of age) accounted for 20% (8) of the cases where brain death criteria were met and for 31.58% of all organ donors. The mean age for adult effective donors was 39 years and for children 7.46 years.

Those 70-79 years of age were analyzed separately. There were 6 cases where brain death was diagnosed and two of those met the medical criteria for donation. In one, consent had been sought unsuccessfully, leaving only one opportunity for

donation in this advanced age group.

Table 4.6

Characteristics of a potential donor pool by patient's age

Age Group (Years)	Potential Donors (n=85)	Met Brain Death Criteria (n=40)	Met Medical Criteria (n=32)	Consent Given (n=20)
0-9	13	5	4	5
10-19	4	3	3	2
20-29	13	5	5	3
30-39	10	7	7	4
40-49	9	7	6	4
50-59	11	4	4	2
60-69	14	3	3	0
70-79	11	6	(2)*	0

* 2 met medical criteria in the group 70-70, but for this study age > 70 years was seen as too old

Brain Death

The formal brain death form was not filled out in all cases where brain death was said to have been met. However, if there was evidence in the health record by either stating or implying (meaning that brain stem testing was done and the results documented) that brain death had occurred, the case was placed in the brain death group. Furthermore, the apnea test was not done in all of the brain death cases, however, when treatment was discontinued and if cardiac death occurred immediately in the absence of any reported respiratory effort these criteria were thought to have been met.

Brain death was diagnosed using the clinical screen alone in 82.50% of the cases. Blood flow studies were used in two cases where severe facial injuries negated the ability to perform the clinical tests and in one case where pulmonary

function was severely compromised because of severe chest trauma. Electroencephalograms were undertaken in two children as supplementary tests to the clinical screen.

Figure 4.3 shows the time between clinical examinations. The waiting period between clinical examinations was less than four hours for 59% of the cases with a mean waiting period of 4.5 hours for all adults and 11.5 hours for children. In the case of a non-effective donor, cardiac arrest and somatic death occurred shortly after the blood flow studies had been completed. Of those who were effective organ donors (19), the mean time from the cerebral catastrophe to the first declaration was 29 hours. While declaration within 24 hours was common in trauma deaths, deaths due to cerebral vascular events were more likely declared beyond 24 hours following the incident.

Table 4.7

Time between cerebral event and first declaration of those that met the criteria for donation (< 70 years of age)

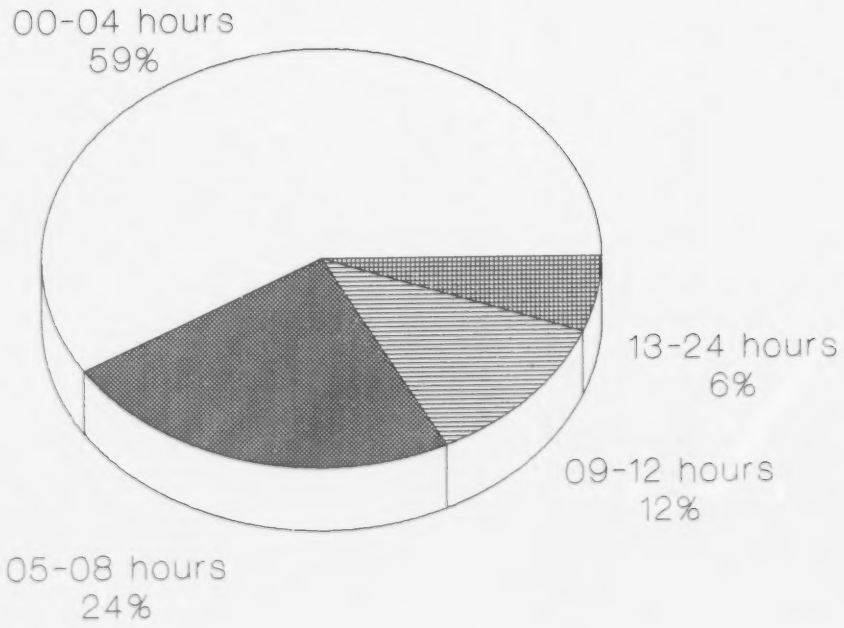
Time	Donor (n=19)	Non-donors (n=13)
06-24 hours	10 (52.63%)	7 (53.85%)
25-48 hours	6 (31.58%)	3 (23.08%)
49-72 hours	2 (12.50%)	2 (15.38%)
4-6 days	1 (5.26%)	1 (7.69%)
7-21 days	0	0

Table 4.7 shows that over 50% of the effective and non-effective donors met brain death criteria within 24 hours of the cerebral event. A full description of the time in

relation to brain death and cross clamp for effective donors is shown in Appendix E.

Figure 4.3

Waiting time between clinical examinations



Cause of Death

The principle cause of death or pre-morbid diagnoses was grouped into three major clusters: trauma, non-traumatic intracerebral vascular catastrophe and hypoxia/anoxia.

Table 4.8

Pre-morbid diagnosis for the non-brain dead and brain dead groups

Pre-morbid diagnosis	Trauma	Intra-cerebral vascular catastrophe	Hypoxia/Anoxia	Total
Group 1				
Non-brain Dead:				
A. Treatment withdrawn	3 (10.71%)	11 (39.29%)	14 (50.00%)	28
B. Cardiac arrest	9 (52.94%)	0 (0.00%)	8 (47.06%)	17
Group 2				
Brain Dead:				
C. Non-effective donor	8 (38.10%)	10 (47.62%)	3 (14.29%)	21
D. Effective donor	7 (36.84%)	10 (52.63%)	2 (10.53%)	19
Total	27 (31.76%)	31 (36.47%)	27 (31.76%)	85

Table 4.8 shows the principle cause of death for the four clusters of potential donors. In group 1, hypoxia/anoxia was the major cause of death for the treatment withdrawn cluster (50%) while for the cardiac arrest cluster it was (52.9%). In the brain dead group, intracerebral vascular catastrophe was the major cause of death for both the non-effective and effective donor groups (47.62%, 52.63%). Of the 15 trauma deaths in group 2, six (40%) were attributed to gunshot wounds to the head and six (40%) were attributed to motor vehicle accidents.

Consent

The possibility of organ donation was considered in 31 of

the 32 cases in which brain dead patients were determined medically suitable for organ donation. Familial consent was granted on 19 (59.38%) occasions, while consent for donation was denied in eight (25%) situations. In one case, the reason the family didn't pursue donation was because the deceased had made arrangements for body donation to the Department of Anatomy. The following reasons were given as to why consent was not obtained for the following four cases: unable to locate the next-of-kin (1), because of being native (1), cardiac arrest occurring before consent was obtained (1) and a decision by an ICU physician not to pursue familial consent because it was thought prolonged hypotension would have ruled out organ suitability.

Table 4.9

Characteristics of potential donors where familial consent denied (n=8)

Case	Age	Sex	Race
1	47	F	A+
2	16	F	NAI++
3	35	F	C+++
4	64	M	NAI
5	32	F	NAI
6	53	M	C
7	28	M	NAI
8	62	M	C

\+ Asian
++ North American Indian
+++ Caucasian

Table 4.9 shows the characteristics of those potential donors where familial consent was denied. In five situations,

the race of the deceased was non-Caucasian, four of these were North American Indian. The race of all effective donors was Caucasian. There was one case where the potential donor was a North American Indian and consent was granted but donation did not occur because of medical contraindications; this involved a pediatric case. In the case where the stated reason for not considering organ donation was 'because of being native', it was not clear whether or not this had been the family's reason or that of the person completing the health care record. There were no cases of restricted permission as to which organs could be donated by either the families granting consent or the Medical Examiner.

It appeared that in most circumstances, the staff physician initiated the discussion on organ donation with the family. In such cases, it was often stated in the progress notes by the staff physician that the family was interested in organ donation and the HOPE Program was notified. It was not always clear when the discussion on donation occurred in relation to that on brain death.

Table 4.10

Health care professional obtaining consent by sex of family member

Family member	Staff Physician	Resident	Registered Nurse	Transplant Coordinator
Male		3	1	3
Female	2	3	4	3

Table 4.10 shows who obtained familial consent. In the 19 effective donor cases, consent was obtained equally by a resident (6) and a HOPE transplant coordinator (6). A registered nurse obtained the consent on five of the remaining cases and a staff physician in two. On six (31.58%) occasions the family initiated the discussion on organ donation.

Summary

The outcomes of this study have been presented in relation to the research questions. While 85 of the 363 audited deaths were identified as potential donors, only 40 met the criteria for brain death. Medical suitability for organ donation occurred in 32 cases of which 19 became effective donors. There were two missed donors, one where organ donation was considered and incorrectly ruled out by an ICU physician without contacting the procurement program. Whereas in the other case no reason could be found and therefore consideration for organ donation appeared to have been over looked. The sample was divided into the following groups: the non-brain dead treatment withdrawn, the non-brain

dead cardiac arrest, the brain dead non-donor and the effective donor.

The donor procurement efficiency rating was 47.5% for those who met the brain death criteria and 59.37% for those who met the medical criteria for organ donation. While infectious conditions were the most common reason brain dead patients did not meet the medical criteria for donation, denied familial consent was the most common reason for non-donation of those that met the medical criteria. Of the 19 effective donors, the donor organ efficiency rating was 59.95%. The most common reason for non-organ utilization was poor organ function.

Eleven potential donors were identified in the extended age group of 70-79 years, of whom two met the medical criteria for donation but neither were effective donors. The mean age for adult effective donors was 39 years and for children 7.46 years. All effective donors were Caucasian while most of the consent denied group were non-Caucasian.

The principle cause of death in the non-brain dead treatment withdrawn group was hypoxia/anoxia while in the cardiac arrest group it was trauma. However, in both the brain dead groups, the major cause of death was intra-cerebral vascular catastrophe. Cardio-respiratory arrest occurred in three effective donors prior to becoming brain dead. On two occasions this occurred outside the hospital. Significant hypoxemia occurred in a further five effective donors

following admission to the ICU. Pre-oxygenation did not appear to have occurred prior to the apnea testing in these ICU cases. While kidney recovery was successful in all of these cases, only six were liver donors, four were heart donors and there were no lung donors.

While staff physicians most often initiated the discussion with the family on organ donation, consent was most often obtained by a registered nurse. Familial consent was granted most often by a female family member and most donors were male. Consent was denied on eight (25%) occasions. In one case, arrangements had previously been made by the deceased for body donation to medical science. On seven occasions the reason for denied consent was unknown.

Clinical brain death screening was the major method used for diagnosing brain death. Supplementary tests were only used when injuries prevented the ability to follow the screening protocol, except in the paediatric group where electroencephalograms were carried out in the children <1 year of age. The mean waiting period between the two declarations was 4.5 hours for adults and 11.5 hours for children. Over 50% of the brain dead patients met the criteria for brain death within 24 hours of suffering the catastrophic cerebral event. The donor remained in the hospital on vital organ support for up to 24 hours after death was declared as the mean time from brain death to vascular cross clamp was 16 hours and 8 minutes and the mean time from the cerebral event

to vascular cross clamp was 43.5 hours.

V. DISCUSSION AND CONCLUSIONS

This chapter begins with a discussion of the study findings in relation to the research questions and the literature pertaining to the characteristics of a potential donor and the effectiveness of organ utilization. The limitations of the study are presented and suggestions for further research are put forward. The chapter ends with concluding remarks about the study design, and the results and implications these findings have for understanding the characteristics of this regional donor pool and measuring the effectiveness of organ utilization.

Discussion of the Findings

Potential Donor Pool

The purpose of this study was to first identify the potential donor pool in a tertiary care transplant centre in Western Canada. Like similar studies, it was found that the potential donor pool was difficult to define in terms of effective organ donor predictability. In order to minimize the exclusion of potential donors from the study, the pre-morbid diagnosis was used as the only restrictive criteria except in the neo-natal group where those weighing less than 3.0 kgs were excluded. Therefore, those with a negligible chance of becoming an effective organ donor were included in the potential donor pool. While 85 potential donors were identified based on the pre-morbid diagnosis, only 32 of those qualified for donation based on the medical acceptance

criteria. This represents 37.65% of the identified potential donors and would therefore indicate that the pre-morbid diagnosis alone is not a good predictor of effective donor rates. Furthermore, previous studies (e.g. Evans et al., 1992) which used the pre-morbid diagnosis as a predictor of organ donor rates may have also over estimated the number of potential donors. This may be in part why there are such discrepancies found between estimates of potential donors and the actual number of effective donors.

Because the hospital where the study was undertaken was not the only source of potential donors for this transplant region, a prediction of the organ donor rate per million population for the whole region was not calculated. However, if a conservative estimate is made assuming that this hospital served one million people, the number of potential donors per million would be 32 which would still be considerably less than that reported for countries such as Austria. Yet, the data in this study suggests that most opportunities for donation were being recognized. Therefore the potential to increase the donation rate to that such as Austria would not be possible by changing legislation.

Efficiency

The Donor Procurement Efficiency Rating (DPER) findings were similar to those reported by Evans et al. (1992) for all potential donors with a high medical probability for donor acceptance (59.37% in this study compared to 59% for the

United States). However, the DPER for potential donors based on the pre-morbid diagnosis alone was considerably lower at 22.35% compared to 37% reported by Evans et al. (1992). Comparisons where there is a high degree of medical probability for donor acceptance can be made between these two studies. This is because, the medical criteria for donor acceptance is recognized as being fairly standard across geographic regions. The inclusion criteria for a potential donor pool based on the pre-morbid diagnosis is more variable. This is because factors such as the potential for meeting both the brain death and medical criteria for donation are less certain and consequently contribute to greater variability in the prediction of donor rates. Therefore, it is suggested that the DPER based on the medical acceptance criteria be the standard for measuring program efficiencies when comparisons are being made among regions.

Intensive Care Unit and Emergency Room Clusters

This study was different from previous studies in four respects: different ICU clusters were studied separately, emergency room deaths were included in the sample, and the non-brain dead group of potential donors and those between 70 and 79 years were analyzed separately. There were considerable differences in the numbers of both potential and effective donors from the different emergency room and ICU clusters. These findings would support previous reports suggesting that the type of ICU creates variances in the

likelihood of donor potential. Furthermore, unlike the findings of Nathan et al. (1991) the recognition of potential donors in the Neurosurgical ICU was not a problem.

This study also looked at the pediatric population as a separate cluster. The DPER from those who were brain dead was nearly twice that of the adult group (80% and 48.39%). This suggests that not only were the parents of the children who die in this hospital willing to agree to organ donation but also, potential donors in this group were being recognized. In the only pediatric case where donation did not occur, the child did not meet the medical criteria; however, familial consent had been obtained. This was also the only case where consent was obtained for a non-Caucasian donor.

Non-Brain Dead Groups

Recent interest concerning the non-heart beating donor has implications for this group of potential donors (Anaise et al., 1990). In this study two groups of non-brain dead donors were examined, those where cardiac arrest had occurred before brain death was determined and those where brain death criteria were not met prior to having the treatment withdrawn. The use of organs from the non-heart beating donor is contingent on the ability to control the warm ischemic damage that occurs in the organs following the cessation of organ perfusion, following death. In the cardiac arrest group, the warm ischemic time can be minimized by implementing core cooling techniques. This allows organ function to be

protected for a limited time until the family decision-making process has concluded (Anaise et al., 1990).

In the treatment withdrawn group there is the potential to increase the effective donor potential by having treatment withdrawn in the operating room. Then, once death had been pronounced by physicians independent from the transplant program the organ recovery procedures would be initiated (Orloff et al., 1994). These two practices have important implications not only of an ethical concern but also in terms of economic resource consumption. It could be argued that both of these practices have the virtue of protecting the rights of the donor family to engage in their choice regarding the option of organ donation (Rapport, 1993). Further credibility for this consideration may be provided through the knowledge that organ donation is supported as an appropriate practice by the vast majority of the population. However, the implications of these practices with regard to different cultural beliefs, the ethical means to this end and the legal implications concerned with interfering with the body of the deceased requires further public debate.

The use of non-heart beating donors also poses implications regarding resource consumption. The cost effectiveness of these practices would have to be considered in relation to the costs of delayed or reduced organ function and successful transplant outcomes. Specially trained individuals would need to be available at any time to initiate

the core cooling procedure. Also, there would be a risk of undertaking the organ recovery procedures only to find out that transplantation cannot proceed because of some medical concern relating to the donor. Regardless of these issues, it may be possible to increase the number of effective donors through the use of non-heart beating donors. However, further debate is required as to the ethical justification for this practice in relation to the rights of the deceased, the family, and the transplant recipient who may be at risk of receiving compromised organs.

Brain Death

The practices of determining brain death were consistent with those previously reported by Norton et al. (1990); however the time interval from cerebral event to pronouncement was much shorter in this study. This would suggest that delayed pronouncement was not a problem in this hospital. This is significant for not only families but also for costs related to an extended length of stay for donors in the ICU. Delays in declaring brain death may add further stress to families or provide them with a false hope of recovery. Efficiencies in declaring brain death may also prevent the loss of potential donors due to infection or cardiac arrest.

Declaration practices in the very small child were different from the remaining sample. The use of adjunct confirmatory tests to the clinical examination were restricted to the use of electroencephalograms in the infant less than

one year. The longer waiting period between declarations for this age group were similar to previously reported cases. This would imply that there is some reticence in applying the adult criteria with the shorter waiting period between testing to this age group.

The incidence of potential donors meeting brain death criteria differed from 1% to 24% depending on the type of ICU. However, there were some cases in the treatment withdrawn group where treatment was withdrawn before brain death testing was undertaken. Two of these involved known intravenous drug users. Also, there was a case where the ICU erroneously ruled a donor as being medically unsuitable without contacting the organ procurement program. This would suggest that decisions are being made by ICU physicians to withdraw treatment. This supports previous findings that the likelihood of brain death in a unit's population is contingent on both the type of ICU and the medical practice within units. However, ICU physicians and nurses should be encouraged to collaborate with the procurement programs to ensure that potential donors are not being lost prior to withdrawing treatment.

In this study the only case where the potential for donation was unrealized occurred in a 52 year old who had been in hospital for five days. This finding was not dissimilar from previous reports where delays in the diagnosis of brain death, increased age and length of stay have been reported as factors associated with missed donors. In this case brain

death was declared 120 hours after admission whereas the mean time from the cerebral event to declaration for the effective donor group was 29 hours.

Consent

While the technique of decoupling the discussion on brain death and on organ donation, as described by Kennedy et al. (1992) was difficult to determine, it was clear that in most cases consent was not obtained during the initial discussion. Staff physicians most often introduced the option of donation to families; however, consent was always obtained at a different interview or time and in most cases it was a nurse who obtained the consent. The incidence of denied consent for those meeting the medical criteria for organ donation represented 25% of the unrealized donors which were predominantly North American Indians. This would suggest that there is a need to look more closely at the cultural meaning of organ donation and transplant therapy for this group. In particular, there is a need to examine their understanding of the donation process, and the incidence of disease requiring transplant therapy amongst their population. Previous researchers (Morris, Slaton & Gibbs, 1989) have reported that the highest percentage of denied consent occurs in cases where the time period from injury to death is greater than 72 hours. The findings in this study did not support this.

Effective Donors

Age

In this study the findings showed a number of critical aspects relating to donor age. The first was that although the number of pediatric cases was small, donors in this age group were being identified including those in the neonatal ICU. It also showed that opportunities for new born donation were very small which has important implications for successful heart transplant options in this group.

Secondly, the mean age of effective donors in this study was higher than that reported by Orlowski & Spees (1993). Older donors pose certain concerns especially donors who are over 50 years of age because they are at a greater risk for cancer than those in a younger age group. Consequently there is a need for thorough family and patient histories and physical assessment to alert the transplant coordinator to the level of risk for such underlying disease.

There were 11 potential donors identified in the extended age group of 70 to 79 years, six of these met brain death criteria and two were seen to be medically suitable. This would indicate that there is a small potential for increasing organ donation opportunities in this age group, providing mechanisms to evaluate and exclude significant systemic diseases are pursued.

Efficiency of Organ Utilization

The donor organ efficiency ratings for the different

organ groups were similar to previously reported results. A number of organs were not able to be placed due to a combination of mismatch problems such as donor hepatitis C reactivity, size, and blood group. The practice of transplanting organs where both donor and recipient are reported as being seropositive for hepatitis C is an accepted practice. However, the placement of these organs was seen to be difficult.

The major reason for non-utilization of organs was due to organ damage or poor function. Some further research is required into this matter to ensure that organs are not needlessly wasted.

Implications for the Major Study

This study also determined that the research design would be appropriate for the major study. However, the data collection tool would be modified with refinements to the layout and typeset. Also, the time and date of the organ donation discussion with the family will be omitted as this information was rarely available. The methods used for data analysis will be replicated in the major study.

Limitations of the Study

A larger sample size of both potential donors which meet the medical criteria and effective donors may have provided for greater variability, with the possibility of some variables attaining statistical significance. However, due to the study design a larger sample was not possible. Some data

were unable to be reported such as that concerning the timing of the family discussions. Therefore, it was unclear as to the relation of the discussion of organ donation with the family to successful donation outcomes. The data were collected retrospectively therefore validation of the findings were not possible. Also, the researcher relied on the Medical Records Department to identify all deaths in the units being studied. It was possible that some ICU and emergency room deaths were missed from the master list or that the researcher overlooked cases that may have been important to the sample. Should these omissions have occurred their absence could have influenced the research findings. The absence of standard definitions for describing a donor population also limits comparisons of these data with findings from similar studies.

Implication for Nursing

The results of this study have implications for nursing administration, practice, and research. If the donor is discharged from the hospital system at the time of death, which is the time that the donor met the brain death criteria for the first time, up to 24 hours of care funding is lost. A new classification for the brain dead patient is required to ensure that health care funding continues until the completion of the organ recovery procedures. The post-mortem care on the brain dead patient in both the ICU and operating room is both resource and labour intensive. Hospitals require a mechanism to capture and report this activity to ensure adequate funding

for donor management and organ recovery procedures occur.

The findings from this study showed that nurses play an active role in obtaining consent from the families of potential donors. It is therefore imperative that they are knowledgeable about the processes related to organ recovery and transplantation including the diagnosis of brain death, physiological changes that occur following brain death, the needs of families in crisis, and the practices related to recipient selection and organ distribution. It would also be important for nurses working in the emergency room and ICUs to develop skills in approaching the subject of organ donation with families who are undergoing various grief reactions.

Nursing Research

The scarcity of usable organs and the reluctance of some people to donate, reinforces the need to understand not only the clinical aspects of the donation process but also what motivates people to donate. Because nurses, other than transplant coordinators, are obtaining familial consent it would be useful to know the type of information that nurses share with families about organ donation when obtaining consent. Also, studies looking at families' understanding of the organ donation process and information needs for making an informed decision, would help in the development of a conceptual framework for supporting and caring for family members, who have to make important decisions at a time of crisis. Since the acceptance of brain death by the

medicolegal community in the early 1980's, donor organ recovery has been undertaken while organ perfusion is maintained. In many respects the donor appears like any other patient where the surgical procedures are undertaken in the same manner as if the patient were alive. However, if the practice of recovering organs from a non-heart beating donor were to be reconsidered, the moral, ethical, and economical justification for implementing such a practice would need to be sought.

As most of the cases of denied consent came from North American Indian families, it would be useful to know this cultural group's knowledge and attitudes toward organ donation and transplantation. It would also be important for health educators to develop information packages about organ donation in a way that would be sensitive to the values of different ethnic groups within the community.

Conclusion

A retrospective design was chosen to answer the research questions relating to the characteristics of a potential donor pool and the effectiveness of organ utilization. While 85 potential donors were identified, 40 became brain dead and 32 met the medical criteria for donation. Of those, familial consent was denied in eight cases. The remaining five reasons for unsuccessful organ recovery were: unable to contact next-of-kin, cardiac arrest before organ recovery, because of being North American Indian, no reason and incorrectly assumed

irreversible organ damage due to prolonged hypotension. The remaining 19 were effective organ donors. An adult donor was most likely Caucasian, 39 years of age having died following a non-traumatic intracerebral event.

The findings from the study suggest that donor recognition in the age group 69 years and under is occurring with only two donors being missed. This would suggest that changing laws would not have any great effect on the donor rate. The DPER based on the number of potential donors that met both the brain death and the medical criteria was similar to that reported for the best case scenarios in the United States. A number of organs were not utilized for two main reasons: no suitable recipient and impaired organ function. The adult donor age was higher than that previously reported and the major cause of death for effective donors was cerebral vascular catastrophe. The use of older donors in the 70 to 79 age group has the potential to marginally increase the effective donor rate; however, consideration would need to be paid to the increased risk of systemic diseases such as cancer. The greatest potential for increasing the effective donor pool was found to be in the non-heart beating donor group but broader ethical and economic considerations would be required if such practices were to be considered.

Generalizability of these findings are limited, however comparisons with studies of similar regions would be possible. The greatest limitation of this study was that the sample was

not large enough to detect significant differences amongst the variables being evaluated. Ideas for future research in the areas of nurses' and families' understanding of the donation process were considered. Studies looking at native peoples' understanding and meaning of organ donation and transplantation were also suggested. Furthermore, if the idea for developing a non-heart beating donor program is to be considered, further research would be required into the feasibility and ethical justification of such practices. In this study a strong need to define more clearly the terms used to describe a potential donor and a donor where organs are recovered and transplanted are also identified. Furthermore, the agreement of definitions by practitioners in the area of transplantation would enable meaningful comparisons to be made among programs.

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Appendix A

Major Study

A major study will be carried out following this study. This will include an audit of the health care records on all patients who died in the emergency room and ICU in the five major hospitals in Edmonton from January 1st, 1993 until December 31st, 1993. This study will describe this regional donor pool and measure the effectiveness of organ utilization for this transplant region. This information will be important for transplant programs to identify the potential number of organs that could be available for those patients in end stage organ failure.

Appendix B

Potential Organ Donor Data Sheet

A. **Demographic Information**

Hospital _____ Unit_____ Hospital Chart #_____

Age_____ Date of cerebral event_____

Sex_____ Time of cerebral event_____

Race: ☐ Asian Indian ☐ Black ☐ Caucasian ☐ Filipino ☐ Inuit ☐ Latin American
☐ North American Indian ☐ Unknown ☐ Other (state) _____

B. **Factors Relating to Brain Death**

1. Pre-morbid diagnosis _____
2. Was brain death a potential diagnosis? ☐ Yes ☐ No
3. Were clinical tests for brain death undertaken? ☐ Yes ☐ No
4. Was brain death declared? ☐ Yes ☐ No
5. Declaration of brain death

   1st declaration Date_____ Time_____

   2nd declaration Date_____ Time_____

   Time between 1st and 2nd declaration_____

   Time from cerebral event to 2nd declaration_____

   Confirmation testing ☐ Yes ☐ No

   Type_____

   Indication for confirmatory testing_____

C. **Factors Relating to Consent**

1. Were the family offered the opportunity to consider donation? ☐ Yes ☐ No ☐ Unknown
2. When was donation discussed? Date_____
   Time_____
3. Who approached the family?
   ☐ Chaplain ☐ Nurse ☐ Social Worker ☐ Resident
   ☐ Staff Physician ☐ Procurement Coordinator ☐ Family initiated discussion
4. Was familial consent granted? ☐ Yes ☐ No ☐ Unknown
   If yes, what was the relationship of the individual providing consent to the deceased
   ☐ Mother ☐ Father ☐ Wife ☐ Husband
   ☐ Daughter ☐ Son ☐ Other (state) _____
5. Was there restricted consent by the family? ☐ Yes ☐ No
   If yes, which organs were denied? _____ _____ _____ _____ _____
   Was this a Medical Examiner's case ☐ Yes ☐ No
6. Did the Medical Examiner give consent? ☐ Yes ☐ No
   Did the Medical Examiner give restricted consent? ☐ Yes ☐ No

D. **Clinical Information**

1. Did cardiac arrest occur? ☐ Yes ☐ No
   If yes, pre-admission ☐
   in emergency room ☐
   in intensive care unit ☐
   Did respiratory arrest occur? ☐ Yes ☐ No
   If yes, pre-admission ☐
   in emergency room ☐
   in intensive care unit ☐
2. Hypotension <60mmHg Systolic >5 minutes
   _____Hours _____Minutes
3. Hypoxemia $Pa0_2$ <70mmHg _____Hours _____Minutes

E. **Organ Utilization**

Potential transplantable organs

Right lung ☐___	Heart ☐_____	Right kidney ☐__	Pancreas ☐____
Left lung ☐____	Liver ☐_____	Left kidney ☐__	

Organs recovered

Right lung ☐___	Heart ☐_____	Right kidney ☐__	Pancreas ☐____
Left lung ☐____	Liver ☐_____	Left kidney ☐__	

Factors attributed to non-utilization of organs

Brain death testing not undertaken ..... ☐
Did not meet brain death criteria ..... ☐
Unable to declare brain death (severe head injury/hemodynamically unstable) ..... ☐
Unable to contact next of kin ..... ☐
Consent denied by family ..... ☐
Consent denied by Medical Examiner ..... ☐
Underlying infectious process ..... ☐
Underlying malignancy other than primary brain tumour ..... ☐
Underlying pathophysiology ..... ☐
(grossly abnormal laboratory values or strong past history of systemic disease)
Unknown cause of coma ..... ☐
High risk social history ..... ☐
(IV drug abuse, prostitution, homosexual behaviours)
Hemodynamic instability ..... ☐
Multiorgan failure ..... ☐

Somatic heart death ..... ☐
Direct organ injury ..... ☐
Other ..... ☐

Time from cerebral event to cross-clamp _____Hours _____Minutes
Time from 1st brain death declaration to cross-clamp _____Hours _____Minutes

Comments_____

Appendix C

POTENTIAL ORGAN DONORS
CODE SHEET

A. YEAR

1991	091
1992	092
1993	093

B. HOSPITAL

University of Alberta Hospitals	100
Emergency Room	101
Intensive Care Unit	102
Pediatric Intensive Care Unit	103
Neonatal Intensive Care Unit	104
Neuro Surgical Intensive Care Unit	105
Cardiovascular Intensive Care Unit	106
Coronary Care Unit	107
Royal Alexandra Hospital	200
Emergency Room	201
Intensive Care Unit	202
Pediatric Intensive Care Unit	203
Neonatal Intensive Care Unit	204
Charles Camsell Hospital	300
Emergency Room	301
Intensive Care Unit	302
Grey Nuns Hospital	400
Emergency Room	401
Intensive Care Unit	402
Misericordia Hospital	500
Emergency Room	501
Intensive Care Unit	502

C. SEX

Male	001
Female	002

D. PRE-MORBID DIAGNOSIS

Intracerebral bleed (undifferentiated)	010
Subarachnoid hemorrhage	011
Ruptured cerebral aneurysm	012
Arterio-Venous malformation	013
Cerebral Infarct	014

Closed head injury (undifferentiated) 020
Closed head injury (motor vehicle accident) 021
Closed head injury (motor bike accident) 022
Closed head injury (cycle accident) 023
Closed head injury (skidoo accident) 024
Closed head injury (all terrain vehicle accident) 025
Closed head injury (pedestrian) 026
Closed head injury (blunt trauma) 027
Closed head injury (shaken baby syndrome) 028

Open head injury (undifferentiated) 030
Open head injury (motor vehicle accident) 031
Open head injury (motor bike accident) 032
Open head injury (cycle accident) 033
Open head injury (skidoo accident) 034
Open head injury (all terrain vehicle accident) 035
Open head injury (pedestrian) 036
Open head injury (gunshot) 037
Open head injury (gunshot wound self-inflicted) 038

Toxic poisoning (undifferentiated) 040
Carbon monoxide poisoning 041
Oral ingested drug poisoning 042
Intravenous drug poisoning 043

Cerebral hypoxia (undifferentiated) 050
Birth asphyxia 051
Sudden Infant Death Syndrome 052
Hanging 053
Smoke/toxic gas inhalation 054
Post-cardiac arrest cerebral hypoxia 055
Drowning 056

Primary non-metastasizing brain tumour 060

E. BRAIN DEATH

Declared 003
Not declared 004
    Confirmatory tests
        ECG 005
        Cerebral angiography 006
        Radionuclide scintigraphy 007

F(a). CONSENT

Family consent granted [go to F(b)] 080
Family consent restricted 081
Family denied consent 085
Family consent not documented 086
    Medical Examiner Consent 082
        ME denied consent 083

ME restricted consent 084

F(b). RELATIONSHIP TO DECEASED

Wife 071
Mother 072
Daughter 073
Husband 074
Father 075
Son 076
Other 077
Who approached family?
Chaplain 090
Physician 091
Resident 092
Nurse 093
Procurement Coordinator 094
Social Worker 095
Family initiated discussion 096

G. POTENTIAL TRANSPLANTABLE ORGANS

Right lung 600
Left lung 601
Heart 602
Liver 603
Pancreas 604
Right kidney 605
Left kidney 606
All the above 607

H. ORGANS RECOVERED

Right lung 700
Left lung 701
Heart 702
Liver 703
Pancreas 704
Right kidney 705
Left kidney 706
All the above 707

I. ORGANS TRANSPLANTED

Right lung 800
Left lung 801
Heart 802
Liver 803
Pancreas (islets) 804
Right kidney 805
Left kidney 806
All the above 807

J. FACTORS RELATED TO INABILITY TO RECOVER

Brain death testing not undertaken 900
Did not meet brain death criteria 901
Unable to declare brain death (chronic vegetative state) 902
Unable to contact next of kin 903
Consent denied by family 085
Consent denied by Medical Examiner 083
Underlying infectious process 906
Underlying malignancy other than primary brain tumour 907
Underlying pathophysiology 908
(grossly abnormal laboratory values or strong past history of systemic disease)
Unknown cause of coma 909
High risk social history 910
(IV drug abuse, prostitution, homosexual behaviours)
Hemodynamic instability 911
Multiorgan failure 912
Somatic heart death 913
Direct organ injury 914
Other 915

Appendix D

A description of the non-brain dead cardiac arrest group (n = 17)

Case	Age	Sex	Race	Time from cerebral incident to cardiac death	Pre-morbid diagnosis
1	57	M	C	2 hours	Closed head injury; CA ER
2	20	F	C	45 minutes	Closed head injury MVA; CAOOH
3	22	M	C	2.5 hours	Closed head injury MVA; CAOOH
4	53	M	B	2 hours	Closed head injury MVA; CA ER
5	17	F	C	1 hour 20 minutes	Open head injury; CAOOH
6	28	M	C	20 minutes	Open head injury MBA; CAOOH
7	52	M	C	1 hour	Hanging; CAOOH
8	69	M	C	1 hour 30 minutes	Post-cardiac arrest cerebral hypoxia; CA ER
9	60	M	C	1 hour	Closed head injury Pedestrian/MVA; CAOOH
10	64	F	C	7 hours 20 minutes	Closed head injury MVA; CA OR
11	64	F	C	120 hours	Oral ingested drug poisoning; CA OR
12	21	M	C	6 hours	Closed head injury; CA OR
13	03	M	C	12 hours	Drowning; CA ICU
14	3mon	M	C	12 hours	Sudden infant death syndrome; CA ICU
15	64	M	A	3 hours	Post-cardiac arrest cerebral hypoxia; CA ICU
16	63	F	C	36 hours	Post-cardiac arrest cerebral hypoxia; CA ICU
17	69	F	C	15 hours	Post-cardiac arrest cerebral hypoxia; CA ICU

C Caucasian
B Black
A Arabic
CAOOH Cardiac arrest out of hospital
CA ER Cardiac arrest in emergency room
CA OR Cardiac arrest in operating room
CA ICU Cardiac arrest in intensive care unit

Appendix E

A description of the non-brain dead treatment withdrawn group (n = 28)

Case	Age	Sex	Race	Time from cerebral incident to cardiac death	Treatment Withdrawn	Pre-morbid diagnosis
1	79	M	NAI	40 hours	ICU	Post-cardiac arrest hypoxia
2	72	M	C	28 hours	ICU	Post-cardiac arrest hypoxia
3	63	F	C	10 hours	ICU	Post-cardiac arrest hypoxia; sepsis; multiorgan failure
4	44	M	NAI	96 hours	ICU	Post-cardiac arrest hypoxia; sepsis
5	38	F	C	528 hours	ICU	Oral ingested drug poisoning; sepsis
6	27	F	NAI	192 hours	ICU	Oral ingested drug poisoning; sepsis
7	76	M	O	132 hours	ICU	Intracerebral bleed; pneumonia; family requested no intubation
8	27	M	C	204 hours	ICU	Open head injury; sepsis
9	03	F	C	120 hours	ICU	Post-cardiac arrest hypoxia; sepsis; multiorgan failure
10	09	M	C	96 hours	ICU	Intracerebral bleed
11	02	M	C	30 hours	ICU	Neuro-ectodermal brain tumour
12	56	M	C	270 hours	ICU	Open head injury MVA; sepsis
13	66	M	C	204 hours	ICU	Intracerebral bleed; extracerebral malignancy
14	71	M	C	16 hours	ICU	Intracerebral bleed; thought too old for donation
15	50	M	C	120 hours	ICU	Intracerebral bleed
16	32	M	C	12 hours	ICU	Intracerebral bleed; leukemia
17	63	F	C	192 hours	ICU	Ruptured cerebral aneurysm
18	49	F	C	84 hours	ICU	Ruptured cerebral aneurysm
19	21	M	C	612 hours	ICU	Closed head injury ATVA
20	63	F	C	12 hours	ICU	Post-cardiac arrest hypoxia; DNR order
21	57	F	C	20 hours	ICU	Post-cardiac arrest hypoxia; request compassionate care
22	4 days	F	C	120 hours	ICU	Birth asphyxia
23	3 days	M	NAI	48 hours	ICU	Birth asphyxia
24	4 days	F	NAI	12 hours	ICU	Birth asphyxia
25	34	F	NAI	12 hours	ICU	IV drug poisoning (cocaine)
26	20	M	NAI	72 hours	ICU	AV malformation; IV drug user
27	59	F	C	480 hours	ICU	Ruptured cerebral aneurysm
28	74	F	C	7 hours	ER	Intracerebral bleed

NAI North American Indian
C Caucasian
O Oriental

Appendix F

A description of the brain dead non-donor group (n=21)

Case	Age	Sex	Race	Pre-morbid Diagnosis	Stated Outcome
1	70	M	C	Intracerebral bleed	Too old
2	47	F	O	Intracerebral bleed	Consent denied
3	48	M	C	Intracerebral bleed	Prior arrangement to Dept. of Anatomy
4	32	F	C	Closed head injury	Cardiac arrest
5	62	M	C	Post-cardiac arrest cerebral hypoxia	Prior arrangement to Dept. of Anatomy
6	06	F	NAI	Cerebral anoxia	Infectious process (consent given)
7	44	M	C	Subarachnoid hemorrhage	Prolonged hypotension
8	70	M	C	Ruptured cerebral aneurysm	Too old and prolonged hypotension
9	61	M	C	Ruptured cerebral aneurysm	Unable to locate NOK
10	72	M	C	Closed head injury MVA	Consent denied
11	16	F	NAI	Closed head injury MVA	Consent denied
12	35	F	C	Closed head injury MVA/pedestrian	Consent denied
13	64	M	NAI	Gunshot wound self-inflicted	Consent denied
14	32	F	NAI	Closed head injury MVA	Consent denied
15	24	M	NAI	Open head injury (gunshot)	Because of being NAI
16	72	F	O	Intracerebral bleed	Too old (multiorgan failure)
17	75	F	C	Intracerebral bleed	Too old (multiorgan failure)
18	53	M	C	Intracerebral bleed	Consent denied
19	52	M	C	Ruptured cerebral aneurysm	No reason
20	74	F	C	Post-cardiac arrest cerebral hypoxia	Multiorgan failure, renal/heart, no LFTs; also Report of Death form said "refused"
21	28	M	NAI	Gunshot wound	Consent denied

Appendix G

A description of the brain dead effective donor group

Case	Age	Sex	Race	Pre-morbid Diagnosis	Time cerebral incident to first declaration	Time cerebral event to second declaration	Time between first and second declaration	Time cerebral event to cross clamp	Time first brain death declaration to cross clamp	Organs Consented	Organs Transplanted
1	17	F	C	Closed head injury, trauma	15 hours	21.5 hours	6.5 hours	30 hours	15 hours	2L,H,Li,2K	2K,Li
2	25	F	C	Toxic gas inhalation	8 hours	13 hours	5 hours	26 hours	18 hours	2L,H,Li,2K	2K,H
3	6	F	C	intracerebral bleed	6 hours	14 hours	8 hours	17 hours	11 hours	2L,H,Li,2K	2K
4	6	F	C	Cerebral aneurysm	84 hours	107 hours	23 hours	125 hours	41 hours	2L,H,Li,2K	Li,K
5	9m	F	C	Intracerebral bleed	45 hours	57 hours	12 hours + EEG	60 hours	15 hours	2L,H,Li,2K	2K,Li
6	2d	M	C	Birth asphyxia	54 hours	57 hours	3 hours + EEG	29 hours	12 hours	H	H
7	41	M	C	Subarachnoid hemorrhage	44 hours	47 hours	3 hours	61 hours	17 hours	2L,H,Li,2K	2K,Li
8	37	F	C	Subarachnoid hemorrhage	40 hours	50 hours	10 hours	62 hours	22 hours	2L,H,Li,2K	H,Li,2K
9	34	M	C	Subarachnoid hemorrhage	8 hours	11 hours	3 hours	19 hours	11 hours	2L,H,Li,2K	1K,Li
10	54	F	C	Cerebral aneurysm	20 hours	22 hours	2 hours	36 hours	16 hours	2L,H,Li,2K	2L,H,Li,2K
11	46	M	C	Cerebral aneurysm	15 hours	19 hours	4 hours	28 hours	13 hours	2L,H,Li,2K	2K,Li
12	49	M	C	Closed head injury, MVA	26 hours	30 hours	4 hours	41.5 hours	15.5 hours	2L,H,Li,2K	2K
13	54	M	C	Open head injury, MVA	48 hours	0 (radionuclide scan)	0	59 hours	11 hours	2L,H,Li,2K	2K
14	15	M	C	Open head injury, GSW	23 hours	27 hours	4 hours	41 hours	18 hours	2L,H,Li,2K	2L,H,Li,2K
15	29	M	C	Open head injury, GSW	9 hours	13 hours	4 hours	33 hours	24 hours	2L,H,Li,2K	2K,H,Li
16	42	M	C	Open head injury, GSW	12 hours	16 hours	4 hours	25 hours	13 hours	2L,H,Li,2K	2K,Li
17	33	M	C	Cerebral thrombosis	44 hours	49 hours	5 hours	57.5 hours	13.5 hours	2L,H,Li,2K	2K,H,Li
18	39	F	C	Cerebral thrombosis	42 hours	46 hours	4 hours	55 hours	13 hours	2L,H,Li,2K	2K,H,Li
19	24	M	C	Closed head injury, MVA	10 hours	0 (radionuclide scan)	0	21.5 hours	11.5 hours	2L,H,Li,2K	2K,H,Li
					Mean 29 hours	Mean 35.26 hours	6.15 hours (all) 4.5 hours (adults) 11.5 hours (peds)	Mean 43.5 hours	Mean 16.11 hours		